COURTNEY M. PRICE
VICE PRESIDENT
CHEMSTAR

American Chemistry Council
Good Chemistry Makes It Possible

December 20, 2001

Christine Todd Whitman, Administrator
US EPA
PO Box 1473
Merrifield, VA 22116

Attn: Chemical Right-to-Know Program – Test Plan Submission from Higher Olefins Panel, Polyalphaolefins Task Group

Dear Administrator Whitman:

The American Chemistry Council Higher Olefins Panel, Polyalphaolefins (PAO) Task Group[1] submits for review and public comment its test plan, as well as related robust summaries, for 1-Decene, Tetramer, Mixed with 1-Decene Trimer, Hydrogenated (CAS# 68649-12-7) under the United States Environmental Protection Agency's High Production Volume (HPV) Chemical Challenge Program. The PAO Task Group understands that there will be a 120-day review period for the test plan and that all comments generated by or provided to EPA will be forwarded to the Panel for consideration. The Higher Olefins Panel, PAO Task Group recommends no testing for this substance.

If you have any questions regarding the PAO test plan, the robust summaries, or the Panel's activities associated with the Challenge Program, please contact the manager of the Higher Olefins Panel, Doug Anderson at 703-741-5616 (telephone), 703-741-6091 (telefax) or Doug_Anderson@americanchemistry.com (e-mail).

Sincerely yours,

cc: Higher Olefins Panel

[1] The members of the Higher Olefins Panel Polyalphaolefins Task Group are Chevron Phillips Chemical Company, and, ExxonMobil Chemical Company.

AR201-13433A

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
HIGH PRODUCTION VOLUME
CHEMICAL CHALLENGE PROGRAM

TEST PLAN

For

1-Decene, Tetramer, Mixed with 1-Decene Trimer, Hydrogenated
CAS # 68649-12-7

Prepared by:

American Chemistry Council
Higher Olefins Panel, Polyalphaolefins Task Group

December 18, 2001

EXECUTIVE SUMMARY

The Higher Olefins Panel (Panel) of the American Chemistry Council and the Panel's member companies hereby submit for review and public comment the test plan for 1-decene, tetramer, mixed with 1-decene trimer, hydrogenated (decene tetramer/trimer), CAS number 68649-12-7, under the United States Environmental Protection Agency (EPA) High Production Volume (HPV) Chemical Challenge Program (Program). The Panel's member companies have committed to identify or develop sufficient screening level test data and other information to adequately characterize the HPV Program human health effects, physicochemical, and environmental fate and effects endpoints for decene tetramer/trimer.

Decene tetramer/trimer is a long chain branched alkane (a hydrogenated polyalphaolefin [PAO]). The predominant (~85%) and shortest oligomer present is a C30 (carbon number 30), with a C40 oligomer comprising most of the remainder.

Read across data exist for all HPV Program health effects endpoints from similar long chain branched alkanes. The data for these structural analogs, derived from C8, C10 and/or C12 alpha olefins, demonstrated no evidence of health effects. In addition, there is evidence in the literature that alkanes with 30 or more carbon atoms are unlikely to be absorbed when administered orally. These data are considered to be sufficient to adequately characterize the HPV Program human health effects endpoints and no further health effects testing is proposed.

Data exist from aquatic toxicity and aerobic biodegradation studies with decene tetramer/trimer and for a C8/C10/C12 PAO (1-octene, 1-decene, 1-dodecene copolymer, hydrogenated). The aquatic studies showed that these PAOs did not produce acute toxicity. The lack of aquatic toxicity is likely due to water solubility limitations. The biodegradation data suggest that decene tetramer/trimer can biodegrade to a great extent. Therefore, decene tetramer/trimer should not persist in the environment. These data are considered to be sufficient to adequately characterize the HPV Program aquatic toxicity and biodegradation endpoints for this product, and no further testing is proposed for these endpoints.

Data and/or information to adequately characterize photodegradation, photolysis, hydrolysis, and fugacity endpoints and to develop a physicochemical dataset will be identified and/or developed and summarized in robust summaries.

American Chemistry Council's

HIGHER OLEFINS PANEL, POLYALPHAOLEFINS TASK GROUP

The Higher Olefins Panel, Polyalphaolefins Task Group includes the following member companies:

LIST OF MEMBER COMPANIES

Chevron Phillips Chemical Company LP

ExxonMobil Chemical Company

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TEST PLAN FOR 1-DECENE, TETRAMER, MIXED WITH 1-DECENE TRIMER, HYDROGENATED

TEST PLAN FOR 1-DECENE, TETRAMER, MIXED WITH 1-DECENE TRIMER, HYDROGENATED

I. INTRODUCTION

The Higher Olefins Panel (Panel), Polyalphaolefin Task Group (PAO Task Group) of the American Chemistry Council and the Panel's member companies have committed to identify or develop sufficient screening level test data and other information to adequately characterize the HPV Program human health effects, physicochemical, and environmental fate and effects endpoints for 1-decene, tetramer, mixed with 1-decene trimer, hydrogenated (decene tetramer/trimer, CAS number 68649-12-7), under the United States Environmental Protection Agency (EPA) High Production Volume (HPV) Chemical Challenge Program (Program).

This plan identifies:

- Existing data of adequate quality for decene tetramer/trimer,
- Read across data from structural analogs of this chemical that can be used to characterize selected HPV Program endpoints, and
- Information needed to complete the HPV Program data set for this chemical.

II. BACKGROUND

Decene tetramer/trimer and related polyalphaolefins (PAO) are highly branched isoparaffinic chemicals produced by oligomerization of 1-octene, 1-decene, and/or 1-dodecene. To accomplish this, the alpha olefin fractions are mixed with catalysts in continuous reactors under mild temperature and pressure. Treatment of the reactor effluent removes the catalyst residues. The crude polyalphaolefin mixture is then distilled into appropriate product fractions to meet specific viscosity specifications and hydrogenated. Decene tetramer/trimer is a mixture of hydrogenated oligomers prepared from 1-decene with a viscosity of 4 cSt. The typical composition of decene tetramer/trimer is approximately 85% decene trimer, 13% decene tetramer, and 2% decene pentamer and higher.

A significant amount of toxicity data exists for other structurally analogous fractions (products) distilled from crude polyalphaolefin. These data may be used to characterize the HPV Program endpoints for decene tetramer/trimer. The identification and typical compositions of these structural analogs of decene tetramer/trimer are presented below:

Substance	Composition
1-Decene homopolymer, hydrogenated [decene homopolymer] (CAS 68037-01-4)*	Hydrogenated homopolymer prepared from 1-decene [approximately 5% C10 trimer (C30), 49% C10 tetramer (C40) and 46% C10 pentamer (C50) and higher
1-Decene/1-dodecene copolymer, hydrogenated [decene/dodecene copolymer]	Hydrogenated copolymer prepared from 10% 1-dodecene and 90% 1-decene [C10 oligomers: approximately 33% trimer (C30), 51% tetramer (C40), 16% pentamer (C50) and higher; and C 12 oligomers]

(CAS 151006-60-9)*	
1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated [octene/decene/dodecene copolymer] (CAS 163149-28-8)*	Hydrogenated copolymer prepared from 1-octene, 1-decene, and 1-dodecene
1-Dodecene trimer, hydrogenated [dodecene trimer] (CAS 151006-62-1)*	Hydrogenated trimer prepared from 1-dodecene (C36)

* Not an HPV material

III. EVALUATION OF EXISTING HEALTH EFFECTS DATA

Decene tetramer/trimer is a long chain branched alkane (a hydrogenated polyalphaolefin). The predominant (~85%) and shortest oligomer present is a C30 (carbon number 30), with a C40 oligomer comprising most of the remainder. Read across data exist for all HPV Program health effects endpoints from the following similar long chain branched alkanes derived from a C8, C10, and/or C12 alpha olefins:

- Decene homopolymer
- Decene/dodecene copolymer
- Octene/decene/dodecene copolymer
- Dodecene trimer

The data for these structural analogs of decene tetramer/trimer demonstrated no evidence of health effects. In addition, there is evidence in the literature that alkanes with 30 or more carbon atoms are unlikely to be absorbed when administered orally.

The existing data for analogous substances are considered to be sufficient to adequately characterize the HPV Program human health effects endpoints. No further health effects testing is proposed.

Specific endpoints are addressed below:

A. Mammalian Toxicology Data

1. Physicochemical Properties Relevant to Mammalian Toxicity

The physicochemical data suggest that it is unlikely that significant absorption will occur. If a substance of the size and structure of decene tetramer/trimer is absorbed, then the principal mechanisms of absorption after oral administration are likely to be passive diffusion and absorption by way of the lymphatic system. The former requires both good lipid solubility and good water solubility as the substance has to partition from an aqueous environment through a lipophilic membrane into another aqueous environment during absorption. Absorption by way of the lymphatics occurs by mechanisms analogous to those that absorb

fatty acids and is limited by the size of the molecule. Lipophilicity generally enhances the ability of chemicals to cross biological membranes. Biotransformation by mixed function oxidases often increases the water solubility of a substance; however, existing data suggest that these substances will not undergo oxidation to more hydrophilic metabolites. Finally, a chemical must have an active functional group that can interact chemically or physically with the target cell or receptor upon reaching it. For decene tetramer/trimer, there are no moieties that represent a functional group that may have biological activity.

The water solubilities of a C10 dimer PAO and a C12 trimer PAO were determined to be <1 ppb (Rausina *et al.*, 1996) and < 1 ppt (Seary, 2000), respectively. The partition coefficient for a C12 trimer PAO was determined to be $Log_{10} P_{ow}$ of >7 (Seary, 2000). The US EPA EPIWIN model predicts a water solubility of 1.02×10^{-16} g/L and a $Log_{10}P_{ow}$ of 17.97 for decene tetramer/trimer. The calculated octanol/water partition coefficient value for a representative chemical structure used to model white mineral oil (CAS No: 8042-47-5), as supplied in the IUCLID dossier, is reported as >6.

Given the very low water solubility expected for decene tetramer/trimer, it is extremely unlikely that this product will be absorbed by passive diffusion following oral administration, and the size of the molecule suggests that the extent of lymphatic absorption is likely to be very low. Thus, it is unlikely that significant quantities of decene tetramer/trimer would be absorbed when administered orally.

Although decene tetramer/trimer oligomers are relatively large lipophilic compounds, and molecular size may be a critical limiting determinant for absorption, there is some evidence that these substances are absorbed. However, the lack of observed toxicity in the studies with PAOs suggests that these products are absorbed poorly, if at all. Furthermore, a review of the literature regarding the absorption and metabolism of long chain alkanes indicates that alkanes with 30+ carbon atoms are unlikely to be absorbed (Iling [2000], see robust summary). For example, Albro and Fishbein (1970) examined the absorption of squalane, an analogous C30 product, administered orally to male CD rats and found that essentially all of the squalane was recovered unchanged in the feces.

At the same time, the hydrophobic properties of decene tetramer/trimer suggest that, should they be absorbed, they would undergo limited distribution in the aqueous systemic circulation and reach potential target organs in limited concentrations.

In addition to the general considerations discussed above, the low volatility of decene tetramer/trimer indicates that, under normal conditions of use or transportation, exposure by the inhalation route is unlikely. In particular, the high viscosity of these substances suggests that it would be difficult to generate a high concentration of respirable particles in the air.

2. Acute Mammalian Toxicity of Decene Tetramer/Trimer

Summary of Available Data

Acute toxicity data relevant to decene tetramer/trimer are summarized in Table 1. Three structural analogs have been tested for acute oral, dermal and inhalation toxicity. No deaths were observed at or above the limit doses in these tests of long chain branched alkanes

similar to decene tetramer/trimer.

Acute Oral Toxicity

Analogous PAOs (decene/dodecene copolymer, octene/decene/dodecene homo-polymer, and dodecene trimer) have been adequately tested for acute oral toxicity. There were no deaths when the test materials were administered at doses of 5,000 mg/kg (decene/dodecene copolymer and dodecene trimer) and at 2,000 mg/kg (octene/decene/dodecene copolymer) in rats. Overall, the acute oral LD_{50} for these substances was greater than the 2000 mg/kg limit dose, indicating a relatively low order of toxicity.

Acute Dermal Toxicity

Analogous PAOs (decene/dodecene copolymer, octene/decene/dodecene copolymer, and dodecene trimer) have been tested for acute dermal toxicity. No mortality was observed for any substance when administered at the limit dose of 2000 or 5000 mg/kg. Overall, the acute dermal LD_{50} for these substances was greater than the 2000 mg/kg limit dose, indicating a relatively low order of toxicity.

Acute Inhalation Toxicity

Analogous PAOs (decene homopolymer, decene/dodecene copolymer, and decene trimer) have been tested for acute inhalation toxicity. Rats were exposed to aerosols of the substances at nominal atmospheric concentrations of 2.5, 5.0, and 5.06 mg/L, respectively, for four hours. These levels were the maximum attainable concentrations under the conditions of the tests, due to the low volatility and high viscosity of the test material. No mortality was noted, and all animals fully recovered following depuration. The lack of mortality at concentrations at or above the limit dose of 2.0 mg/L indicates a relatively low order of toxicity for these substances.

Data Assessment and Test Plan for Acute Mammalian Toxicity

Adequate acute toxicity studies have been conducted with four structural analogs of decene tetramer/trimer. These studies involved two species of laboratory animals (rats or rabbits) and three routes of exposure (oral, dermal, and inhalation). The data consistently demonstrate a low order of acute toxicity for PAOs derived from C10 and C12 alpha olefins. The similarity in the low order of toxicity for these substances is consistent with their similar chemical structure and physicochemical properties and supports the scientific justification for read across to decene tetramer/trimer. Consequently, no additional acute toxicity testing is proposed for the HPV Challenge Program.

Table 1. Summary of Existing Acute Mammalian Toxicity Data for Decene Tetramer/Trimer and Structural Analogs

PRODUCT	Oral LD50 (rats)	Dermal LD50 (rats/rabbits)	Inhalation LC50 (rats)
1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated (CAS 68649-12-7)	RA	RA	RA
1-Decene homopolymer, hydrogenated (CAS 68037-01-4)*	--	--	>2.5 mg/L (4 hr)
1-Decene/1-dodecene copolymer, hydrogenated (CAS 151006-60-9)*	>5 g/kg+	>2 g/kg+ (rats)	>5.0 mg/L (4 hr)
1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (CAS 163149-28-8)*	>2 g/kg	>2 g/kg+ (rabbits)	--
1-Dodecene trimer, hydrogenated (CAS 151006-62-1)*	>5 g/kg	>2 g/kg (rats)	>5.06 mg/L (4hr)

* Not an HPV material; included to support assessment.
+ Based on ExxonMobil Chemical Company Material Safety Data Sheet information – robust summary is not provided.

3. Genotoxicity of Decene Tetramer/Trimer

Summary of Genotoxicity Data

A summary of the genotoxicity information for analogous PAOs (decene homopolymer, octene/decene/dodecene copolymer, dodecene trimer; and decene/dodecene copolymer [*prepared from 10% C12 and 90% C10 alpha olefins; approx. 33% trimer and 51% tetramer, 16% pentamer and higher*]) is presented in Table 2. Either bacterial or mammalian gene mutation assays, *in vitro* chromosomal aberration assays, or *in vivo* chromosomal aberration assays have been conducted for these substances. Neither mutagenicity nor clastogenicity were exhibited by any of these substances in the referenced *in vivo* or *in vitro*

tests, with or without metabolic activation.

Bacterial Gene Mutation Assay

Analogous PAOs (decene homopolymer, octene/ decene/dodecene copolymer, dodecene trimer, and decene/dodecene copolymer) have all been adequately tested in Bacterial Reverse Mutation Tests. Decene homopolymer (with 10 ppm of an antioxidant) was also negative in the modified bacterial gene mutation assay. All tested substances were negative for mutagenic activity, with and without metabolic activation.

Mammalian Cell Gene Mutation Assay

A structural analog of decene tetramer/trimer, dodecene trimer, was negative in the Chinese hamster ovary cell HGPRT gene mutation assay, with and without metabolic activation.

In vitro Chromosomal Aberration Assay

Three structurally analogous PAOs (decene homopolymer, octene/decene/dodecene copolymer, and dodecene trimer) were adequately tested in *in vitro* chromosomal aberration assays. Decene homopolymer and octene/decene/dodecene copolymer were tested in the Chinese hamster ovary (CHO) cell assay. Dodecene trimer was evaluated in the *in vitro* chromosome aberration test in human lymphocytes. The results of these studies, performed with and without metabolic activation of the test material, were negative for clastogenicity.

In vivo Chromosomal Aberration Assays

The structural analog, decene homopolymer, has been adequately tested in an *in vivo* chromosomal aberration assay. Male and female rats treated dermally with test material at doses of 800 and 2000 mg/kg/day, five days per week for 13 weeks were used to assess cytotoxicity to red blood cells. The bone marrow and peripheral blood were collected from the rats following the 13-week period. The test material was not cytotoxic to red blood cell formation, nor did it induce a statistically significant increase in the formation of micronucleated PCEs or NCEs in bone marrow or peripheral blood cells of dermally treated rats. Decene/dodecene copolymer and dodecene trimer were also negative in mouse micronucleus assays after intraperitoneal (i.p.) administration.

Data Assessment and Test Plan for Genotoxicity

Four structural analogs of decene tetramer/trimer have been tested for genotoxicity (viz., gene mutations and chromosomal aberrations). The assays included gene mutations in bacterial cells, *in vitro* chromosomal aberrations in mammalian cells, and *in vivo* chromosomal aberrations in rats and mice. The data consistently demonstrated no evidence of genotoxicity regardless of metabolic activation. This suggests that decene tetramer/trimer and all structural analogs lack genotoxicity due to their similarity in chemical structures and physicochemical properties and supports scientific justification for bridging data gaps within this HPV Challenge Program.

By bridging these data, decene tetramer/trimer has been evaluated adequately for

genotoxicity, and no additional testing is proposed for the HPV Challenge Program.

Table 2. Summary of Existing Genotoxicity Data for Decene Tetramer/Trimer and Structural Analogs

PRODUCT	Bacterial Gene Mutation Test	Mammalian Cell Gene Mutation Test	In Vitro Mammalian Cell Chromosome Aberration Tests	In Vivo Mammalian Chromosome Aberration Test
1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated (CAS 68649-12-7)	RA	RA	RA	RA
1-Decene homopolymer, hydrogenated (CAS 68037-01-4)*	Negative+	--	Negative- (CHO cell assay)	Negative (Rat micronucleus, repeat dermal)
1-Decene/1-dodecene copolymer, hydrogenated (CAS 151006-60-9)*	Negative	--	--	Negative (Mouse micronucleus, i.p.)
1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (CAS 163149-28-8)*	Negative	--	Negative (CHO cell assay)	--
1-Dodecene trimer, hydrogenated* (CAS 151006-62-1)	Negative	Negative (CHO HGPRT)	Negative (Human lymphocyte assay)	Negative (Mouse micronucleus, i.p.)

* Not an HPV material, included to support assessment.
RA Read across.
\+ Based on ExxonMobil Chemical Company Material Safety Data Sheet Information – robust summaries are not provided.

4. Repeated-Dose Toxicity of Decene Tetramer/Trimer

Summary of Repeated-Dose Toxicity Data

The HPV Challenge Program requires that a repeated-dose toxicity study and a reproductive toxicity study be performed or bridged to structurally analogous substances. No adequate repeated-dose toxicity studies have been located available for decene tetramer/trimer; however, adequate data for repeated-dose toxicity are available for three structural analogs of this product.

One 28-day oral toxicity study in rats, one 90-day dermal and two 90-day dietary studies in rats, and a dermal carcinogenicity study in mice exist for the analogous substance, decene homopolymer. A rat oral combined reproductive toxicity and 91-day systemic toxicity study was also conducted with decene homopolymer [see Reproductive/Developmental section for reproductive toxicity phase information]. In addition, 28-day rat oral toxicity studies exist for two structurally analogous substances (dodecene trimer and octene/decene/dodecene copolymer); and a 90-day rat dermal toxicity study exists for octene/decene/dodecene copolymer.

Results from these studies show a low order of repeated dose toxicity and are presented in Table 3.

Repeated-Dose Dermal Toxicity

Octene/decene/dodecene copolymer was applied to clipped backs of male and female rats five days per week for approximately four weeks at dose levels of 0 (untreated control), 125, 500, and 2000 mg/kg/day. In addition, two satellite groups, one exposed to octene/decene/dodecene copolymer at 2000 mg/kg/day and one that received no treatment, were observed for two weeks following the four weeks of dosing. The test material produced no signs of skin irritation at the site of exposure. After four weeks of dosing, there was a slight decrease in body weight gain for males dosed at 2000 mg/kg/day. Female weight gain was not affected. No microscopic changes were associated with treatment. The NOEL for systemic toxicity for this study was 500 mg/kg/day. However, the observed changes in body weight and hematology were marginal and were only observed in the satellite group and not the treatment group. Therefore, the NOAEL for systemic toxicity in this study was 2000 mg/kg/day.

Decene homopolymer was applied to the skin of Sprague-Dawley rats, five days a week for thirteen weeks at dose levels of 800 and 2000 mg/kg/day. Body weights of the high-dose males were slightly less than those of the controls (9% less). There were no other indications of systemic toxicity. The substance caused only slight effects (slight flaking) at the application site on the skin. Based on the above results, the NOAEL for decene homopolymer following topical application in rats is 2000 mg/kg/day.

Decene homopolymer produced no treatment-related tumors in C3H mice treated with a 50 µl/application twice weekly for 104 weeks. In addition, survival (56%) was greater than in any other group, including the untreated control.

Repeated-Dose Oral Toxicity

Decene homopolymer was evaluated in a 28-day oral gavage rangefinding toxicity study at dose levels of 0, 500, 2500, and 5000 mg/kg/day in Sprague-Dawley rats. No significant clinical signs indicative of systemic toxicity were observed. No gross pathological changes were noted. Histological evaluation of the liver revealed no adverse effects. Based on the above results, the NOAEL for 1-decene homopolymer is 5,000 mg/kg/day in Sprague-Dawley rats.

Decene homopolymer was evaluated in a 90-day oral (feeding) toxicity study at dose levels

of 500, 5000 and 20,000 ppm in Sprague-Dawley rats. No clinical signs indicative of systemic toxicity were observed. None of the major organ systems showed any detectable treatment-related changes. Based on the above results, the NOAEL for 1-decene homopolymer is 20,000 ppm in Sprague-Dawley rats.

Decene homopolymer was evaluated in a 90-day oral (feeding) toxicity study at dose levels of 200 and 20,000 ppm in Fischer 344 rats. No clinical signs indicative of systemic toxicity were observed. No adverse effects were observed for the hematology results with the substance. Marginal serum chemistry effects were observed for the male rats following 90 days of treatment with the substance in the diet at 20,000 ppm. None of the major organ systems showed any detectable treatment-related changes. Based on the above results, the NOAEL for decene homopolymer is 20,000 ppm in Fischer 344 rats.

A rat oral combined reproductive toxicity and systemic toxicity study was also conducted with decene homopolymer, with Sprague-Dawley rats at levels of 0, 100, 500, and 1000 mg/kg/day [see Reproductive/Developmental section for reproductive toxicity phase information]. In this study, parental animals were dosed for 4 weeks prior to mating and during mating (males and females), during gestation and to day 20 post-partum (females). The offspring were dosed for 91 days starting on day 22 post-partum. No treatment related toxicity was observed in the F0 male and female rats. The F1 pups did not demonstrate any test article related toxicity during parturition and lactation. In the F1 rats during the 91-day toxicity phase, repeated oral exposure of decene homopolymer produced no evidence of any adverse effects on clinical observations, organ weights, gross or histopathology, clinical chemistry or hematology endpoints. Based on these data, the NOAEL for repeated dose toxicity was 1000 mg/kg/day, the highest concentration tested.

Oral administration of the structural analog, decene trimer, to Sprague-Dawley rats for a period of twenty-eight consecutive days at a dose level of 1000 mg/kg/day produced no treatment-related changes in the parameters measured. The NOAEL was 1000 mg/kg/day.

Data Assessment and Test Plan for Repeated-Dose Toxicity

Eight repeated-dose toxicity studies using two different animal species, rats and mice, and oral and dermal routes of administration have been conducted with three structural analogs of decene tetramer/trimer. These data suggest that decene tetramer/trimer and all structural analogs exhibit a low order of toxicity following repeated applications, due to their similarity in chemical structures and physicochemical properties, and support scientific justification for bridging data gaps within this HPV Challenge Program.

By bridging these data, decene tetramer/trimer has been evaluated adequately for repeated exposure toxicity, and no additional testing is proposed for the HPV Challenge Program.

Table 3. Summary of Existing Repeated-Dose Toxicity Data for Decene Tetramer/Trimer and Structural Analogs

PRODUCT	28-Day (Sprague-Dawley rat)	90-Day (Sprague-Dawley/Fischer 344 rat)	Chronic (mouse)
1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated (CAS 68649-12-7)	RA	RA	RA
1-Decene homopolymer, hydrogenated (CA 68037-01-4)*	NOAEL >5000 mg/kg/day (Rangefinding Study, Sprague-Dawley rat) (oral gavage)	NOAEL >20,000 ppm (Sprague-Dawley rats) (Dietary) NOAEL >2000 mg/kg/day+ (Sprague-Dawley rats) (Dermal) NOAEL >20,000 ppm (Fischer 344 rats) (Dietary) NOAEL >1000 mg/kg/day (Sprague-Dawley rats) (oral gavage)	104-Week Dermal Carcinogenicity (Negative)
1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (CAS 163149-28-8)*		NOAEL 2000 mg/kg/day (Sprague-Dawley) (Dermal)	--
1-Dodecene trimer, hydrogenated* (CAS 151006-62-1)	NOAEL >1000 mg/kg/day (oral gavage)	--	--

* Not an HPV material, included to support assessment.

RA Read across.

\+ Based on ExxonMobil Chemical Company Material Safety Data Sheet Information – robust summary is not provided.

5. Reproductive/Developmental Toxicity of Decene Tetramer/Trimer

No adequate reproductive or developmental toxicity studies have been located for decene tetramer/trimer; however, data are available for the structural analog, decene homopolymer. Results from these studies show a low order of reproductive/ developmental toxicity and are presented in Table 4.

Developmental Toxicity

Decene homopolymer (with 10 ppm of an antioxidant) was administered once daily on gestation days 0-19 via dermal application to presumed-pregnant rats at doses of 0, 800, and 2000 mg/kg/day. Dermal administration of the test material did not adversely affect parameters of reproductive performance during gestation, nor did it adversely affect *in utero* survival and development of the offspring. The NOAEL in this study for developmental parameters was 2000 mg/kg/day.

Reproductive Toxicity

A rat oral combined reproductive toxicity and systemic toxicity study was conducted with decene homopolymer. This study with rats was conducted as part of a 91-day toxicity study with offspring of parents administered decene homopolymer by oral gavage. Parents and offspring received decene homopolymer at 0, 100, 500, and 1000 mg/kg/day. The parental males were dosed for a minimum of 4 weeks prior to mating and throughout the 15-day breeding period. Parental females were dosed for 4 weeks prior to mating, through pregnancy and until sacrifice at day 20 post-partum. The offspring were dosed for a minimum of 91 days starting on day 22 post-partum. No effects on fertility were seen. The NOAEL for reproductive toxicity was 1000 mg/kg/day, the highest concentration tested. The lack of effects on fertility in this study or effects on reproductive organs in this or other subchronic studies with closely related chemicals indicates that decene tetramer/trimer is unlikely to exert effects on reproduction.

Table 4. Summary of Existing Reproductive/Developmental Toxicity Data for Decene Tetramer/Trimer and Structural Analogs

PRODUCT	Reproductive (Rat)	Developmental (Rat)
1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated (CAS 68649-12-7)	RA	RA
1-Decene homopolymer (CAS 68037-01-4)*	Combined Repeated Exposure and Reproduction Oral Toxicity Study NOAEL 1000 mg/kg/day (Oral gavage)	Maternal/Fetal NOAEL = 2000 mg/kg/day (Dermal)

* Not an HPV material, included to support assessment.
RA Read across.

Data Assessment and Test Plan for Reproductive/Developmental Toxicity

No studies have been located where decene tetramer/trimer was tested for reproductive/developmental toxicity. However, a dermal developmental toxicity study and an oral reproductive toxicity study with rats were conducted with a structural analog, 1-decene homopolymer. In addition, toxicity to reproductive organs has been assessed in

repeated-dose studies with structural analogs. These data are considered adequate to address the potential developmental/reproductive toxicity of decene tetramer/trimer and no additional developmental/reproductive toxicity tests are proposed.

IV. EVALUATION OF EXISTING PHYSICOCHEMICAL AND ENVIRONMENTAL FATE DATA AND PROPOSALS FOR ADDRESSING THESE ENDPOINTS

A. Physicochemical Properties

Physicochemical data (i.e., melting point, boiling point, vapor pressure, water solubility, and Kow) for decene tetramer/trimer will be calculated using the EPIWIN© model (EPIWIN, 1999), as discussed in the EPA document titled *The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program* (U.S. EPA, 1999a). In addition, measured data for some of these endpoints will also be provided for decene tetramer/trimer or structural analogs. Where possible, the measured and calculated data will be presented together in robust summaries for comparative purposes. Table 5 lists selected measured physicochemical data as the data appeared on the material safety data sheets for decene tetramer/trimer or analogous chemicals.

Table 5. Selected Physical Properties of Decene Tetramer/Trimer and Analogs

CAS NUMBER	CHEMICAL NAME	BOILING POINT (° C)	VAPOR PRESSURE (mm Hg @ 20° C)	SPECIFIC GRAVITY	WATER SOLUBILITY	LOG K_{ow}
68649-12-7	1-Decene tetramer/trimer	>316	<0.1	0.82	< 1 ppt* <0.4 ppm**	>7.0*

* Read across value for an analogous chemical, 1-dodecene trimer, hydrogenated

** Read across value for an analogous chemical, 1-octene, 1-decene, 1-dodecene copolymer, hydrogenated

B. Biodegradation

Biodegradation data were developed for decene tetramer/trimer using the EPA Shake Flask Method (EPA 560/6-82-003, CG-2000) with an unacclimated sewage/soil inoculum. At initial test material concentrations of 10 and 20 mg of carbon per liter, 54% and 49% biodegradation, respectively, were measured after 28 days (Mobil Oil Corporation, 1992c). These data show that decene tetramer/trimer can biodegrade to a great extent, which suggests that it will not persist in the environment.

C. Photodegradation, Hydrolysis, and Fugacity

1. Photodegradation – Photolysis (Direct)

Direct photochemical degradation occurs through the absorbance of solar radiation by a chemical substance. If the absorbed energy is high enough, then the resultant excited state of the chemical may undergo a transformation. Simple chemical structures can be

examined to determine whether a chemical has the potential for direct photolysis in water. First-order reaction rates can be calculated for some chemicals that have a potential for direct photolysis using the procedures of Zepp and Cline (1977). The UV light absorption of decene tetramer/trimer will be evaluated to identify if it has the potential to degrade in solution. A technical discussion will be prepared for this endpoint that summarizes the results of this evaluation.

2. Photodegradation – Photolysis (Indirect)

Photodegradation can be measured (U.S. EPA, 1999b) (EPA identifies OECD test guideline 113 as a test method) or estimated using models accepted by the EPA (U.S. EPA, 1999a). An estimation method accepted by the EPA includes the calculation of atmospheric oxidation potential (AOP). Atmospheric oxidation as a result of hydroxyl radical attack is not direct photochemical degradation, but rather indirect degradation. AOPs can be calculated using a computer model.

Polyalphaolefins, such as the one in this test plan, have a low potential to volatilize to air. In air, volatilized chemicals can undergo reactions with photosensitized oxygen in the form of ozone and hydroxyl radicals. The computer program AOPWIN (atmospheric oxidation program for Microsoft Windows) (EPIWIN, 1999) is used by OPPTS (Office of Pollution Prevention and Toxic Substances). This program calculates a chemical half-life based on an overall OH- reaction rate constant, a 12-hr day, and a given OH- concentration. Although decene tetramer/trimer is not expected to partition to the air to a significant degree based on its low vapor pressure, this calculation will be performed for a representative chemical structure of this product, and the results summarized within the technical discussion on direct photolysis.

3. Stability in Water (Hydrolysis)

Hydrolysis of an organic chemical is the transformation process in which a water molecule or hydroxide ion reacts to form a new carbon-oxygen bond. Chemicals that have a potential to hydrolyze include alkyl halides, amides, carbamates, carboxylic acid esters and lactones, epoxides, phosphate esters, and sulfonic acid esters (Neely, 1985). Stability in water can be measured (US EPA, 1999b) (EPA identifies OECD test guideline 111 as a test method) or estimated using models accepted by the EPA (US EPA, 1999a).

The product in this test plan is a hydrocarbon. That is, it consists entirely of carbon and hydrogen. As such, it is not expected to hydrolyze at a measurable rate. A technical document will be prepared that discusses the potential hydrolysis rate of this product, the nature of the chemical bonds present, and the potential reactivity of this class of chemicals with water.

4. Chemical Distribution in the Environment (Fugacity Modeling)

Fugacity based multimedia modeling can provide basic information on the relative distribution of chemicals between selected environmental compartments (i.e., air, soil, sediment, suspended sediment, water, biota). The U.S. EPA has acknowledged that computer modeling techniques are an appropriate approach to estimating chemical partitioning (fugacity is a calculated endpoint and is not measured). A widely used fugacity

model is the EQC (Equilibrium Criterion) model (Mackay, 1996). EPA cites the use of this model in its document titled *Determining the Adequacy of Existing Data* (US EPA, 1999b), which was prepared as guidance for the HPV Program.

In its document, EPA states that it accepts Level I fugacity data as an estimate of chemical distribution values. The input data required to run a Level I model include basic physicochemical parameters; distribution is calculated as percent of chemical partitioned to 6 compartments (air, soil, water, suspended sediment, sediment, biota) within a unit world. Level I data are basic partitioning data that allow for comparisons between chemicals and indicate the compartment(s) to which a chemical is likely to partition.

The EQC Level I is a steady state, equilibrium model that utilizes the input of basic chemical properties including molecular weight, vapor pressure, and water solubility to calculate distribution within a standardized regional environment. This model will be used to calculate distribution values for a representative structure of the product in this test plan. A computer model, EPIWIN, version 3.04 (EPIWIN, 1999), will be used to calculate the properties needed to run the Level I EQC model that are not available as measured values.

V. EVALUATION OF AQUATIC TOXICITY DATA

Aquatic toxicity endpoints for the HPV Program include acute toxicity to a freshwater fish and invertebrate, and toxicity to a freshwater alga. Decene tetramer/trimer is not expected to produce acute toxic effects to freshwater fish and invertebrates, or toxic effects to algae, based on data developed for this product and an analogous product, octene/decene/dodecene copolymer (Table 6).

Table 6. Summary of Aquatic Toxicity Data for PAO Anchor Studies

PRODUCT	Freshwater Fish Acute (96-hr)	Marine Fish Acute (96-hr)	Marine Invertebrate Acute (96-hr)	Freshwater Invertebrate Acute (48-hr)	Freshwater Alga (72-hr)
1-Decene, tetramer, mixed with 1-dodecene trimer, hydrogenated	LL_0 = 5010 mg/L (RA)	LL_0 = 5002 mg/L	LL_0 = >5002 mg/L	EL_0 = 5220 mg/L(RA)	EL_0 = 5220 mg/L (RA)

RA Read across data from 1-octene, 1-decene, 1-dodecene copolymer, hydrogenated.

Experimental toxicity test results for decene tetramer/trimer are reported for a marine fish, sheepshead minnow (*Cyprinodon variegatus*), and a marine invertebrate, mysid shrimp (*Mysidopsis bahia*) (Mobil Oil Corporation, 1992a,b). Additional experimental toxicity test results for octene/decene/dodecene copolymer are also reported for a freshwater fish, rainbow trout (*Oncorhynchus mykiss*), a freshwater invertebrate (*Daphnia magna*), and a freshwater alga (*Selenastrum capricornutum*, now known as *Pseudokirchneriella subcapitata*) (Stonybrook, 1994a,b,c). The data from these studies show that these products do not produce toxicity to these organisms for the selected endpoints. The reason

for the lack of toxicity is most likely due to the low water solubility of these products.

The water solubility of decene tetramer/trimer is very low. Although no data specifically for this product has been located, there are data from a soil adsorption/desorption study for a product similar to decene tetramer/trimer. The results from this study show that octene/decene/dodecene copolymer has a water solubility less than 0.4 mg/L (Stonybrook, 1995), which was the lowest limit of detectability in this study. The water solubility of another similar product, dodecene trimer, was determined to be <1 ppt, the limit of detection in the assay (Seary, 2000). By structural comparison, these data suggest that decene tetramer/trimer also has low water solubility. This is not unexpected for a product whose chemical components range in molecular weight from approximately 422 for a C30 component to 562 for a C40 component.

VI. TEST PLAN SUMMARY

Sufficient data exist for decene tetramer/trimer and analogous chemicals to adequately characterize the HPV Program human health effects, aquatic toxicity, and biodegradation endpoints for decene tetramer/trimer. No additional testing is proposed for these endpoints.

The following modeling and technical discussions will be developed for the physicochemical properties and other environmental fate endpoints:

- Calculate physicochemical data as described in the EPA document titled, *The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program* for selected chemical components of the product in this test plan. Provide measured data where readily available.
- Prepare a technical discussion on the potential of the polyalphaolefin product in this test plan to photodegrade. Calculate AOP values for a representative chemical structure of the product in this test plan.
- Prepare a technical discussion on the potential of the polyalphaolefin product in this test plan to hydrolyze.
- Calculate fugacity data for a representative chemical structure of the product in this test plan.

The assessment plan for 1-decene, tetramer, mixed with 1-decene trimer, hydrogenated, is presented in Table 7.

Robust summaries of existing studies (except as noted in Tables 1-3) of health effects, aquatic toxicity, biodegradation, and physicochemical data are attached (Appendix 1). Summaries of the other environmental fate and physicochemical endpoints will be developed once the data and analyses have been completed. This test plan is expected to provide adequate data to characterize the human health effects, physicochemical, and environmental fate and effects endpoints for decene tetramer/trimer under the HPV Program.

Table 7. Assessment Plan for 1-Decene, Tetramer, Mixed with 1-Decene Trimer, Hydrogenated, Under the HPV Program (Except as noted in Tables 1-3, robust summaries for existing studies are provided in Appendix 1).

Chemical	Human Health Effects						Ecotoxicity			Physico-chemical	Environmental Fate			
	Acute Toxicity	Genetic Point Mut.	Genetic Chrom.	Sub-chronic	Develop-mental	Repro-duction	Acute Fish	Acute Inver-tebrate	Alga Toxicity		Photo-degra-dation	Hydro-lysis	Fugacity	Biodeg-radation
1-Decene, Tetramer, Mixed with 1-Decene Trimer, Hydrogenated [85% trimer, 13% tetramer, 2% pentamer and higher] CAS # 68649-12-7	RA	RA	RA	RA	RA	RA	√	√	RA	CM/M	CM/TD	TD	CM	√
1-Decene, Homopolymer, Hydrogenated CAS # 68037-01-4	√	--	√	√	√	√	--	--	--	--	--	--	--	--
1-Decene/1-Dodecene Copolymer, Hydrogenated [C10 oligomers: approximately 33% trimer (C30), 51% tetramer (C40), 16% pentamer (C50) and higher; and C 12 oligomers] CAS # 151006-60-9	√	√	√	--	--	--	--	--	--	--	--	--	--	--
1-Octene, 1-Decene, 1-Dodecene Copolymer, Hydrogenated CAS # 163149-28-8	√	√	√	√	--	--	√	√	√	√*	--	--	--	--
1-Dodecene Trimer, Hydrogenated CAS # 151006-62-1	√	√	√	√	--	--	√	√	√	√**	--	--	--	--

√ Adequate existing data available

√* Water solubility

√** Water solubility and $Log_{10}P_{ow}$

TD Technical discussion proposed

CM Computer modeling proposed

M Identify measured data where available (a robust summary for water solubility is provided with this test plan)

Shaded areas denote non-HPV substances

RA Read across data from structural analogs: 1-octene, 1-decene, 1-dodecene copolymer, hydrogenated; 1-dodecene trimer, hydrogenated; 1-decene/1-dodecene copolymer and/or 1-decene homopolymer, hydrogenated (see Tables 1- 6)

VII. REFERENCES

Albro, P W, Fishbein, L. 1970. Absorption of aliphatic hydrocarbons by rats. Biochim. Biophys. Acta 219, 437-446.

EPIWIN. 1999. Estimation Program Interface for Windows, version 3.02. Syracuse Research Corporation, Syracuse, NY, USA.

Illing, P. 2000.On the Potential Absorption and Metabolism of Alkane 4. Conducted by Paul Illing Consultancy Services, Wirral, UK for Chevron Chemical Company. Unpublished report submitted to the UK Health and Safety Executive for EU Level 2 New Chemical Notification of Alkane 4 [1-dodecene trimer, hydrogenated].

Mackay, D., A. Di Guardo, S. Paterson, and C. E. Cowan. 1996. Evaluating the Environmental Fate of a Variety of Types of Chemicals Using the EQC Model. Environ. Toxicol. Chem. 15:1627-1637.

Mobil Oil Corporation, Environmental and Health Sciences Laboratory. 1992a. Static-Renewal 96-hour Acute Toxicity Study of the Water Soluble Fraction (WSF) of SHF-41 to *Mysidopsis bahia*. Unpublished Report.

Mobil Oil Corporation, Environmental and Health Sciences Laboratory. 1992b. Static 96-hour Acute Toxicity Study of SHF-41 to Sheepshead Minnow. Unpublished Report.

Mobil Oil Corporation, Environmental and Health Sciences Laboratory. 1992c. Aerobic Biodegradation Study of SHF-41. Unpublished Report.

Neely, W. B. 1985. Hydrolysis. In: W. B. Neely and G. E. Blau, eds. Environmental Exposure from Chemicals. Vol I., pp. 157-173. CRC Press, Boca Raton, FL, USA.

Rausina, G.A., W.R. Biggs, P.M. Stonebraker, and E.A. Crecelius. 1996. Using semi-permeable membrane devices (SPMDs) to estimate bioconcentration potential of petroleum additives. 10th Int. Colloquium on Tribology, Stütgart, 9-11 January 1996.

Seary, M. 2000.Determination of Water Solubility and Octanol/Water Partition Coefficient of C12 Trimer Polyalphaolefin. Unpublished report conducted by Integrated Laboratory Technologies, Chevron Research and Technology, Richmond, CA, USA.

Stonybrook Laboratories, Inc. 1994a. Static 72-hour Inhibition Study of the WAF of MCP-1602 to *Selenastrum capricornutum*. Unpublished Report.

Stonybrook Laboratories, Inc. 1994b. Static 96-hour Acute Toxicity Study of MCP-1602 to Rainbow Trout. Unpublished Report.

Stonybrook Laboratories, Inc. 1994c. . 48-hour Static Acute Toxicity Study of the WAF of MCP-1602 to *Daphnia magna*.. Unpublished Report.

Stonybrook Laboratories, Inc. 1995. Solubility in Water. Unpublished Report.

U.S. EPA. 1999a. The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program. OPPT, EPA.

U.S. EPA. 1999b. Determining the Adequacy of Existing Data. OPPT, EPA.
Zepp, R. G., and D. M. Cline. 1977. Rates of Direct Photolysis in the Aqueous Environment. Environ. Sci. Technol. 11:359.366.

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APPENDIX 1

Robust Summaries for 1-Decene, Tetramer, Mixed with 1-Decene Trimer, Hydrogenated, and Structurally Analogous PAOs

TABLE OF CONTENTS

BIODEGRADATION (CAS NO.: 68649-12-7)

Test Substance:	CAS No.: 68649-12-7; 1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated
Method/Guideline:	USEPA EPA 560/6-83-003, CG-2000
Year (guideline):	1982
Type (test type):	Aerobic Aquatic Biodegradation
GLP:	Yes
Year (study performed):	1992
Inoculum:	Domestic activated sludge
Exposure Period:	28 days
Test Conditions: • **Note: Concentration prep., vessel type, replication, test conditions.**	Activated sludge and test medium were combined prior to test material addition. The media consisted of a mineral salt solution, activated sludge, and distilled water. The test system utilized 2.0L Erlenmeyer flasks as test vessels. The test and reference materials were added to duplicate test vessels followed by enough volume of test medium to yield a 1.0 L final volume, after inoculum addition. Mixed liquor was added to each flask to give a final dry sludge solids concentration of 30 mg/L. In addition, 0.1 g of soil was added to each flask followed by 1 mL of yeast extract solution (15 mg yeast extract per 100 mL of distilled water). The flasks were closed with neoprene stoppers containing a 10 mL KOH trap and an inlet and outlet port. The flasks were then placed on a rotary shaker at 25°± 3°C at approximately 150 rpm. Potential biodegradability was evaluated at two test material loadings of approximately 10 mg/L and 20 mg/L of carbon. Sodium benzoate (positive control) concentration was approximately 20 mg/L of carbon. Twice per week, the flasks were monitored for spent NaOH and evolved carbon dioxide (CO_2) was determined by titration.
Results: **Units/Value:** • **Note: Deviations from protocol or guideline, analytical method.**	On day 28, 53.5 and 49.2% biodegradation was achieved in the 10 and 20 mg/L carbon loadings, respectively. The positive control (sodium benzoate) degraded by 84% by day 28. No excursions from the protocol were noted.
Conclusion:	The test material was not readily biodegradable.

Reliability:	(1) Reliable without restriction
Reference:	Mobil Oil Corporation, Environmental and Health Sciences Laboratory. 1992. Aerobic Biodegradation Study, SHF-41, Study No. 65226.
Other (source):	ExxonMobil Biomedical Sciences, Inc.

FISH ACUTE TOXICITY (CAS NO.: 68649-12-7)

Test Substance:	CAS No.: 68649-12-7; 1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated
Method/Guideline:	Fish Acute Toxicity Test (EPA 560/6-82-002; OECD 203)
Type (test type):	Fish Acute Toxicity Test; Dispersion Test
GLP:	Yes
Year (study performed):	1992
Species:	Sheepshead Minnow (*Cyprinodon variegatus*)
Analytical Monitoring:	No
Exposure Period:	96 hour
Statistical Method:	Binomial Probability Analysis (Stephan, et al., 1978)
Test Conditions: • **Note: Concentration prep. vessel type, volume, replication, water quality parameters, environmental conditions, organisms supplier, age, size, weight, loading.**	Individual Oil/Water Dispersion (OWD) systems were prepared for each treatment level. The test system was designed to maintain the test substance as a dispersion of small droplets throughout the water column. The test substance was added volumetrically, via graduated cylinder, directly to the dispersion system. Each test chamber was a 10-gallon glass aquaria with 30 liters of water, and was equipped with a vertically mounted, motor-driven impeller assembly. The impeller assembly, consisting of 3-blades on a 10-inch stainless steel shaft, was housed in a 2-inch diameter PVC cylinder with 4 horizontal apertures near the bottom. Water and test substance spilling into the top of the cylinder were expelled through the apertures at the bottom. The OWD systems operated continuously for the duration of the test. Twenty fish were randomly assigned to each chamber. No renewal of the test solutions was performed during the test. Test temperature was 19.5 - 20.0 Deg C., lighting was 16 hours light : 8 hours dark. Dissolved oxygen ranged from 6.7 to 7.0 mg/L, and pH ranged from 8.1 to 8.4 during the study. Salinity ranged from 18.4 - 21.9 ppt. Fish were not fed during the study. Fish Mean Wt.(Control) = 0.55g; mean standard length = 2.9cm, test organism loading = 0.37 g of fish/L.

Results: **Units/Value:** • **Note: Deviations from protocol or guideline, analytical method, biological observations, control survival.** **Results continued**	96-hr LL0 = 5002mg/L, based on nominal loading levels. Loading Level. % Mortality @ 96 hr. Control 10 98 mg/L 0 492 mg/L 0 1011 mg/L 0 2023 mg/L 0 5002 mg/L 0
Conclusion:	
Reliability:	Code 1, Reliable without restriction
Reference:	Mobil Oil Corporation, Environmental and Health Sciences Laboratory. 1992. Static 96-hour Acute Toxicity Study of SHF-41 to Sheepshead Minnow, Study No. 65227.
Other (source):	ExxonMobil Biomedical Sciences, Inc.

INVERTEBRATE ACUTE TOXICITY (CAS NO.: 68649-12-7)

Test Substance:	CAS No.: 68649-12-7; 1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated
Method/Guideline:	Mysid Acute Toxicity Test (EPA 560/6-82-002)
Type (test type):	Mysid Acute Toxicity Test - Static Renewal
GLP:	Yes
Year (study performed):	1992
Species:	Mysid Shrimp (*Mysidopsis bahia*)
Analytical Monitoring:	No
Exposure Period:	96 hour

Statistical Method:	Binomial Probability Analysis (Stephan, et al., 1978)
Test Conditions: • **Note: Concentration prep. vessel type, volume, replication, water quality parameters, environmental conditions, organisms supplier, age, size, weight, loading.**	Individual Water Accomodated Fractions (WAF) were prepared for each treatment solution twenty-four hours prior to test initiation. WAFs were stirred with magnetic stir bars and stirplates in glass aspirator bottles containing 1 L of test water. A measured amount of the test material was pipetted onto the water surface of each bottle. All aspirator bottles were covered with parafilm to minimize evaporation. Stirring produced a vortex of less than 25% of the depth of the solution. After the stirring/settling period, the aqueous phase (WAF) was drawn from the outlet at the bottom of each aspirator bottle and split into two replicates of 400 mL each. This procedure was repeated to prepare fresh solutions at 24, 48, and 72 hours. Test chambers were 1 L Pyrex crystallizing dishes. Ten mysids were randomly assigned to each chamber. Test temperature was 19.8 - 20.6 Deg C; lighting was 16 hours light : 8 hours dark. Dissolved oxygen ranged from 6.2 to 7.2 mg/L and pH was approximately 8.4 during the study. Salinity ranged from 19.0 - 22.0 ppt. Mysids were fed newly hatched *Artemia* spp. nauplii (approximately 24 hours old) *ad libitum* prior to and daily during the test. Mysids were four to six days old at study initiation.
Results: **Units/Value:** • **Note: Deviations from protocol or guideline, analytical method, biological observations, control survival.** **Results continued**	96-hr LL0 = 5002mg/L, based on nominal loading levels. Loading Level — % Mortality @ 96 hr. Control — 5 82 mg/L — 5 574 mg/L — 15 1066 mg/L — 5 2050 mg/L — 10 5002 mg/L — 0
Conclusion:	
Reliability:	Code 1, Reliable without restriction
Reference:	Mobil Oil Corporation, Environmental and Health Sciences Laboratory. 1992. Static-Renewal 96-hour Acute Toxicity Study of the Water Soluble Fraction (WSF) of SHF-41 to *Mysidopsis bahia*,

	Study No. 65228.
Other (source):	ExxonMobil Biomedical Sciences, Inc.

Acute Inhalation Toxicity (CAS NO.68037-01-4)

Test Substance CAS No.	**1-Decene Homopolymer, hydrogenated** **68037-01-4**
Method/Guideline Type of Study GLP Year Species/strain Sex No. of animals/sex/dose Route of administration Dose/Concentration Levels Exposure Time	Other Acute Inhalation Yes 1988 Sprague-Dawley rats Males/Females 10/sex Inhalation - Aerosol 0, 0.48, and 2.5 mg/L 4 hours
Remarks on Test Conditions	The test atmosphere was generated with a Laskin nebulizer to aerosolize the test material. The concentration of the aerosol was controlled by varying the design of the nebulizer, the air pressure, and air flow. A glass elutriator was used to remove large particles from the aerosol to maximize the percentage of respirable particles in the aerosol stream. The aerosol concentration in the chamber was determined gravimetrically. Young adult rats were exposed for 4 hours to 0, 0.48, or 2.5 mg/L of aerosolized test material for 4 hours. Half of the animals in each group were sacrificed the day after exposure and half were sacrificed two weeks after exposure. On the day of sacrifice, animals were necropsied, wet and dry weights of kidneys, liver, and right middle lung lobe were measured, and selected tissues were preserved for histopathology. From the control and high dose groups, the following tissues were examined microscopically: nasal turbinates, tracheobronchial lymph nodes, left kidney, liver, and all gross lesions.
Results	LC_{50} > 2.5 mg/L
Remarks	The mean aerosol concentrations for the exposed groups were 0.48 and 2.5 mg/L. The mass median aerodynamic diameter of the generated particles was 1.1 μm. All animals appeared normal during the exposure, although less than one-half of the animals in the high-dose group could be observed because of poor visibility within the test chamber due to the high aerosol concentration. No animals died during the exposure, or during the following two-week observation period. No toxicologically significant changes were observed for clinical signs and mean body weights of the animals following exposure. Organ weights were not affected by exposure. The lung was the only organ with treatment-related changes. At the 1-day sacrifice, dark depressed or discolored areas were observed

Conclusions	in 3 animals from the middle dose group and 6 animals from the high dose group. However, since none of these lesions were found at the 2-week sacrifice, the effects appeared to be reversible. Acute focal inflammation was observed in 2 animals from the 0.5 mg/L group and 6 animals from the 2.5 mg/L group. These foci were present in the respiratory tract (along the route of exposure) and resolved by 2 weeks following the exposure. Under the conditions of this study, decene homopolymer has a low order of acute toxicity via the inhalation route of exposure.
Data Quality	1 - Reliable without restrictions.
Reference	Final Report on Acute Inhalation Toxicity of Decene Homopolymer, (1987) Mobil Environmental and Health Science Laboratory
Date last changed	December 2001

Repeated Dose Toxicity (CAS No.: 68037-01-4)

Test Substance	**1-Decene Homopolymer, hydrogenated**
CAS No.	**68037-01-4**
Method/Guideline	Other
Type of Study	Subchronic Range-finding Study
GLP	Yes
Year	1990
Species/strain	Sprague Dawley
Sex	Females
No. of animals/sex/dose	5/dose
Route of administration	Oral gavage
Frequency of treatment	5 days per week for 4 weeks
Dose/Concentration Levels	0, 500, 2500, 5000 mg/kg/day
Control group and treatment	2 Control groups: Sham treatment and untreated
Remarks on Test Conditions	Female rats (5/dose), in addition to a sham-gavage control group and an untreated control group, were individually housed and allowed free access to food and water. Animals were checked for morbidity and mortality at least once daily. Animals were weighed immediately before the first dosing and approximately weekly thereafter. Macroscopic findings were noted at necropsy, but organ weights were not measured. The liver was fixed and examined microscopically.
Results	NOAEL = 5000 mg/kg/day
Remarks	No deaths occurred during the study. There were no significant changes in body weight. The only clinical signs that could be attributed to the test material were oily staining around the anus and soft stool. No gross pathological changes were observed in any of the groups. Histological evaluation of the liver revealed no adverse effects. The results of this study were used to set the doses for a 90-day feeding study.

Conclusions	Under the conditions of this study, decene homopolymer has a low order of subchronic toxicity via the oral route of administration.
Reliability	2 - Reliable with restrictions - rangefinding study
Reference	Range-Finding Study: Oral Administration of Unadditized decene homopolymer to rats (1990), Performed by Mobil Environmental Health and Safety Department.
Date last changed	December, 01

REPEATED DOSE TOXICITY (CAS NO.: 68037-01-4)

Test Substance	**1-Decene Homopolymer, hydrogenated**
CAS No.	**68037-01-4**
Method/Guideline	FDA Guideline: Guidelines for Subchronic Oral Toxicity Studies EPA Guideline: Health Effects Test Guidelines: Subchronic Exposure
Type of Study	90-Day Oral Administration in Diet
GLP	Yes
Year	1990
Species/strain	Sprague-Dawley Rats
Sex	Males/Females
No. of animals/sex/dose	20/sex/dose
Route of administration	Diet
Frequency of treatment	Ad libitum, 13 weeks
Dose/Concentration Levels	20,000 ppm in diet
Control group and treatment	Control Diet
Remarks on Test Conditions	Rats (20/sex/dose) were fed lab chow containing 0, 500, 5000, and 20,000 ppm decene homopolymer for 90 days. Diet was prepared one week prior to initiation of the study and every other week thereafter. Feed homogeneity and stability analyses were performed on each batch. Animals had continuous access to test diet and water. The amount of food consumed was determined three times per week. Each animal was observed daily during the course of the study for clinical signs, mortality, and moribundity. Blood samples were collected prior to treatment and both blood and urine samples were collected during weeks 5 and 13. At the end of the exposure period, animals received ophthalmologic examinations and were euthanized and necropsied with a complete gross examination. Fresh organ weight was determined in 10 males and 9 females. From each rat, 50 tissues were preserved. From these, tissues of the control and high dose groups were examined by light microscopy. Gross pathology data were evaluated statistically using by ANOVA.
Results	NOAEL = 20,000 ppm
Remarks	All rats survived to study termination. No clinical signs indicative of systemic toxicity were observed during this study. The test material did not adversely effect body weight gain or food consumption. Urinalysis and ophthalmologic exam data did not indicate any treatment-related effects. No statistically significant changes were observed in the hematology analysis between the control and treated animals. Statistically significant differences were found between the serum

	chemistry data from the untreated and treated animals. Specifically, a linear relationship was found between the dose and serum level for albumin/globulin ratio in males and for inorganic phosphorous in females. When compared to historical serum reference values, only the dose-response curve for the inorganic phosphorous at the highest dose fell outside the normal range of the historical data. Animals in the study exhibited no signs of compound related ocular disease. Urinalysis did not reveal any treatment-related changes. There were no changes in organ weight that were deemed to be due to treatment. No effects on the enteric tract were observed. Mean liver weight and microscopic examinations of the liver did not vary significantly between the high dose and control rats. None of the major organs or organ systems, including male and female reproductive organs, showed any detectable treatment-related changes.
Conclusions	Decene homopolymer did not produce any toxicologically significant effects under the conditions of this study.
Reliability	1 - Reliable without restrictions
Reference	90-Day Oral Administration of Unadditized Decene Homopolymer in the Diet of Rats. (1990) Performed by Mobil Environmental Health and Safety Department.
Date last changed	December, 01

REPEATED DOSE TOXICITY (CAS NO.: 68037-01-4)

Test Substance	**1-Decene Homopolymer, hydrogenated**
CAS No.	**68037-01-4**
Method/Guideline	OECD 408
Type of Study	90-Day Subchronic
GLP	Yes
Year	1995
Species/strain	Fischer 344 Rat
Sex	M/F
No. of animals/sex/dose	10/sex/group
Route of administration	Diet
Dose/Concentration Levels	200, 20,000 ppm
Control group and treatment	Control Diet
Remarks on Test Conditions	Decene Homopolymer at dose levels of 200 and 20,000 ppm was administered in the diet to male and female Fischer 344 rats. Diet was prepared 1-week prior to administration and every two weeks thereafter. Food consumption was measured three times per week. Virus-free Fischer 344 rats were received at about 4 weeks of age. Prior to treatment, blood samples were drawn and animals received an ophthalmologic examination. Following a 2-week quarantine, animals were randomly allocated to treatment groups (10/sex/group), individually housed, and received test material in the diet at 200 and 20,000 ppm. Food and water were available *ad libitum*. Animals were checked for morbidity and mortality at least once daily. Hematology and serum chemistry analyses were performed on blood samples collected prior to treatment, and

	during weeks 5 and 13. Ophthalmoscopic examinations of the eyelids, bulbar conjunctiva, cornea, iris, anterior chamber, and lens were performed. Necropsies were performed at the end of the study and tissues were collected for histopathologic evaluation. Results were analyzed by ANOVA and associated by F-test.
Results	NOAEL > 20,000 ppm
Remarks	No clinical signs were observed during the study. Aside from two animals that died during the 13-week blood collection, all animals survived until the end of the study. In general the amount of food consumed by treated animals was comparable to controls and body weight gain was normal. Hematology results were normal in both treated and control animals. However, there were statistically significant differences in the serum chemistry data, (glucose in males, and sodium, phosphorous, and calcium in females) between the control and treated animals. These differences were considered marginal and the biological significance was not clear. Ophthalmoscopic examinations revealed no abnormalities. The test material did not produce any significant findings at necropsy. In addition, there were no significant treatment-related changes in the liver or mesenteric lymph nodes.
Conclusions	Decene Homopolymer poses a low order of subchronic toxicity.
Data Quality	1 - Reliable without Restrictions
Reference	90-Day Oral Feeding Study in Fischer 344 Rats with Hydrogenated Polyalpha Decene in the Diet, (1995) Performed by Stonybrook Laboratories, Inc. for Mobil Corporation.
Date last changed	December, 2001

REPEATED DOSE TOXICITY (CAS NO. 68037-01-4)

Test Substance	
Remarks	**1-Decene Homopolymer, hydrogenated (31.3% trimer, 45.0% tetramer, 23.7% pentamer and higher), CAS# 68037-01-4**
Method	
Method/guideline followed	Other
Test type	Combined repeated exposure and reproduction oral toxicity study
GLP	Yes.
Year	1994
Species	Rat
Strain	Crl:CD® (Sprague-Dawley) BR VAF/Plus
Route of administration	Oral gavage
Duration of test	Parental males were dosed for 4 wks prior to mating, through 15-day mating period. Parental females were dosed for 4 wks prior to mating, through pregnancy and until day 20 post-partum. Offspring were dosed for 91 days starting on day 22 post-partum.
Doses/concentration levels	0, 100, 500, 1000 mg/kg/day
Sex	F0: 30 males, 30 females per group; F1: 20 males, 20 females per group.

Frequency of treatment	7 days/week
Control group and treatment	Polyethylene glycol 400, 5 ml/kg
Post exposure observation period	Not applicable.
Statistical methods	Adult body weights, body weight gains, feed consumption, organ weights, clinical chemistry data and appropriate hematologic data were evaluated by ANOVA. When significance was observed with ANOVA, group by group comparisons were performed using Dunnett's Test or a modified version of Dunnett's Test. All tests were two-tailed with a minimum significance level of 5% comparing the control group to each treatment group.
Test Conditions	The study design included a 91-day main study for repeated dose toxicity end points and a reproductive toxicity study (summarized separately). Animals utilized for the 91-day toxicity study were offspring of animals administered the test article for 4 weeks prior to mating, during mating, and, for females, through gestation and lactation day 20. Parental animals: Animals were observed daily for overt signs of toxicity. Males were weighed weekly. Females were weighed weekly prior to mating and on gestation days 0,7,14, and 20 and lactation days 1,7,14, and 21. Food consumption was measured on the same days as body weights, except during cohabitation. All animals were subjected to a gross necropsy. Offspring: Animals were observed daily for overt signs of toxicity. Body weights and food consumption were measured weekly. Ophthalmology examinations were performed on all animals prior to initiation of dosing and near study conclusion. Blood samples were obtained on the day of euthanasia for evaluation of clinical pathology parameters. A gross necropsy examination was performed on all animals. Organ weights were obtained for liver, kidneys, thyroid/parathyroid, adrenal glands, gonads and brain. Histopathologic examinations were performed on all control and high animals and animals found dead during the study. The study also contained reproductive and developmental toxicity endpoints (summarized separately).
Results	
NOAEL (NOEL)	1000 mg/kg/day.
LOAEL (LOEL)	Not applicable.
Remarks	No treatment related toxicity was observed in the F0 male and female rats. The F1 pups did not demonstrate any test article related toxicity during parturition and lactation. In the F1 rats during the 91-day toxicity phase, clinical observations representing minor gastrointestinal disturbances were seen in all groups and were judged to be vehicle related. No apparent test article related clinical observations were noted. Transient changes in body weights, weight gain, food consumption, hematology parameters and organ weights were seen at a few intervals, but were not considered to be biologically meaningful. A statistically significant increase in prothrombin time was seen in the males of the 1000 mg/kg/day group, however, this change did not correlate with a decrease in platelets, gross necropsy findings or any lesions noted histopathologically, Therefore, this increase in prothrombin time was not considered to be biologically meaningful.

Conclusions	Repeated oral exposure of 1-decene homopolymer, hydrogenated, to male and female Sprague Dawley rats at levels of 0, 100, 500, and 1000 mg/kg/day produced no evidence of any adverse effects on clinical observations, organ weights, gross or histopathology, clinical chemistry or hematology endpoints. Based on these data, the no-observable-effect level (NOEL) for repeated dose toxicity was 1000 mg/kg/day, the highest concentration tested.
Data Quality	
Reliabilities	Klimish value = 1 (Reliable without restrictions).
References	Daniel, E.M. (1994) An oral (gavage) 91-day toxicity study of EthylFlo 166 in rats with an in utero exposure phase. Report of Springborn Laboratories, Inc., Spencerville, OH, conducted for Albemarle Corporation, Baton Rouge, LA.
Other	
Last changed	31-October-01

Genetic Toxicity 'In Vivo' (CAS No.: 68037-01-4)

Test Substance	**1-Decene Homopolymer, hydrogenated**
CAS No.	**68037-01-4**
Method	Other
Type of Study	Micronucleus/Subchronic Dermal
GLP	Yes
Year	1985
Species/Strain	Rats
No. of animals/sex/dose	15/sex/dose
Remarks on Test Conditions	15 Rats/sex/dose were exposed dermally to Decene Homopolymer daily, 5 days per week for 13 weeks at doses of 0, 800, or 2000 mg/kg/day. Subchronic dermal exposure was selected as the exposure method because it is the most relevant route of exposure for industrial use. At the end of the 13-week period, appropriate tissue was harvested for micronucleus evaluation. Femurs were taken from 5 rats/sex/dose and peripheral blood smears were made. Slides were air dried, fixed in methanol and then stained with acridine orange. The incidence of micronuclei was determined per 1000 polychromatic erythrocytes (PCEs) or normochromatic erythrocytes (NCEs). Potential cytotoxicity of the test material was monitored and determined as the ratio of polychromatic and normochromatic erythrocytes. Results were analyzed by ANOVA.
Results	NOAEL > 2000 mg/kg/day
Remarks for Results	Decene Homopolymer was not cytotoxic to red blood cell formation as shown by the ratio of PCEs to NCEs. No statistically significant increases in the formation of micronucleated polychromatic or normochromatic erythrocytes were observed at any dose.
Conclusions	Decene Homopolymer is not clastogenic following subchronic dermal application to rats.
Data Quality	2 - Reliable with restrictions - not a guideline study

Reference	Micronucleus assay of bone marrow and peripheral red blood cells from rats treated via dermal administration of Synthetic Hydrocarbon-Hydrogenated Polyolefins, (1985), Mobil Environmental and Health Science Laboratory.
Date last changed	December, 01

TOXICITY TO REPRODUCTION (CAS NO.: 68037-01-4)

Test Substance	
Remarks	**1-Decene Homopolymer, hydrogenated (31.3% trimer, 45.0% tetramer, 23.7% pentamer and higher), CAS# 68037-01-4**
Method	
Method/guideline followed	Other
Test type	Combined repeated exposure and reproduction oral toxicity study
GLP	Yes.
Year	1994
Species	Rat
Strain	Crl:CD® (Sprague-Dawley) BR VAF Plus
Route of administration	Oral gavage
Duration of test	Parental males were dosed for 4 wks prior to mating, through 15-day mating period. Parental females were dosed for 4 wks prior to mating, through pregnancy and until day 20 post-partum. Offspring were dosed for 91 days starting on day 22 post-partum.
Doses/concentration levels	0, 100, 500, 1000 mg/kg/day
Sex	F0: 30 males, 30 females per group; F1: 20 males, 20 females per group.
Frequency of treatment	7 days/week
Control group and treatment	Polyethylene glycol, 5 ml/kg
Post exposure observation period	Not applicable.
Statistical methods	Continuous data, including body weights, weight gain, feed consumption, pre-implantation loss, gestation length, mean live litter size, implantation scar counts, clinical pathology and organ weights, were analyzed by ANOVA. When significance was observed with ANOVA, group by group comparisons were performed using Dunnett's Test or a modified version of Dunnett's Test. Count data were analyzed using Chi-Square test for copulation, fertility and pup sex ratios, the number of live and dead pups per group on lactation day 0, and pup survival after lactation day 0. Mann-Whitney U Test was utilized for resorptions. All tests were two-tailed with a minimum significance level of 5% comparing the control group to each treatment group.
Test Conditions	The study design included a 91-day main study for repeated dose toxicity end points (summarized separately) and a reproductive toxicity study. Animals utilized for the 91-day toxicity study were offspring of animals administered the test article for 4 weeks prior to mating, during mating, and, for females, through gestation and lactation day 20.

	Parental animals: Animals were observed daily for overt signs of toxicity. Males were weighed weekly. Females were weighed weekly prior to mating and on gestation days 0,7,14, and 20 and lactation days 1,7,14, and 21. Food consumption was measured on the same days as body weights, except during cohabitation. All animals were subjected to a gross necropsy. In females, the number of implantation scars were recorded. Mating, conception and fertility indices were evaluated. Offspring: The F1 offspring were evaluated for sex, viability, growth and development during lactation and the post-weaning period.
Results	
NOAEL (NOEL)	1000 mg/kg/day
LOAEL (LOEL)	Not applicable.
Remarks	There were no treatment related effects on the parental animals or on any of the reproductive parameters evaluated in this study, at any dose level. These included measures of reproductive performance (mating, conception and fertility , time to mating, gestation length, litter size), offspring survival (gestation and postnatal survival indices, percent pre- and post-implantation loss), pup body weight and pup sex ratio. No treatment related effects on reproductive organ weight or histopathology were seen in the 91-day toxicity study with the F1 animals.
Conclusions	Repeated oral exposure of 1-decene homopolymer, hydrogenated, to male and female Sprague Dawley rats at levels of 0, 100, 500, and 1000 mg/kg/day produced no evidence of adverse effects on any measures of reproductive function. Based on these data, the no-observable-effect level (NOEL) for reproductive toxicity was 1000 mg/kg/day, the highest concentration tested.
Data Quality	
Reliabilities	Klimish value = 1 (Reliable without restrictions).
References	Daniel, E.M. (1994) An oral (gavage) 91-day toxicity study of EthylFlo 166 in rats with an in utero exposure phase. Report of Springborn Laboratories, Inc., Spencerville, OH, conducted for Albemarle Corporation, Baton Rouge, LA.
Other	
Last changed	31-October-01

DEVELOPMENTAL TOXICITY (CAS NO.: 68037-01-4)

Test Substance	**1-Decene Homopolymer, hydrogenated**
CAS No.	**68037-01-4**
Method/Guideline	Other
Type of Study	Developmental

GLP	Yes
Year	1988
Species/strain	Sprague-Dawley Rats
Sex	Female
No. of animals/sex/dose	15 females/dose
Route of administration	Dermal
Vehicle	None
Frequency of Treatment	Once daily
Dose/Concentration Levels	0, 800, and 2000 mg/kg
Statistics	ANOVA, Fisher's Exact Test, F-test, Student-Newman-Keul's multiple comparison test.
Remarks on Test Conditions	Male and female rats were housed together at a ratio of 1:1. Females were examined daily for evidence of mating. Pregnant female rats were randomly assigned to dose groups (15/dose) and were dosed once daily at 0, 800, and 2000 mg/kg during GD 0-19. The test material was applied once daily to the clipped, intact dorsal skin of the rat. The test material contained 10 ppm of an antioxidant. The dermal route of exposure was chosen since it is the most relevant route of exposure in industrial applications. Rats were fitted with Elizabethan-style collars to minimize ingestion of the test material. The collars were replaced as needed throughout the gestation period. The application sites were not covered. To ensure that the rats were dosed correctly, the amount of test material to be applied to each rat was calculated using the most recently recorded body weight, dose level, and the density of the material. Control rats were clipped and collared in the same fashion as the treated rats and stroked with the tip of a syringe. Throughout gestation, animals were monitored daily for changes in appearance, behavior, or excretory function and for any signs of mortality or morbidity. Blood samples were collected from females on GD 20. The quantity or activity of 22 serum components in collected blood samples was analyzed by a flame photometer. A gross necropsy was performed on each female and the ovaries and uterus of each rat were excised and examined grossly. The following parameters were recorded: the number of corpora lutea per ovary, uterine weight, number and location of implantations, early and late resorption, and live and dead fetuses. Each fetus was gendered, weighed, measured, and grossly examined for anomalies. From each litter, half of the fetuses were examined for visceral anomalies and half of the fetuses were examined for skeletal anomalies.
Results	NOAEL = 2000 mg/kg/day
Remarks	Rats in the two treatment groups showed minimal if any irritation at the site of application of the test substance. There were no differences in food consumption during gestation between treated and control rats. Although there was a significantly smaller weight gain during gestation interval 13-16 in the high dose group, the overall weight gain for the entire gestational period was not significantly different from the controls. Serum triglycerides and albumin showed statistically significant changes between control and treated groups, however the changes did not occur in a dose-dependent fashion. It was concluded that dermal treatment of

	female rats during gestation had no significant effect on normal serum chemistry. At necropsy, there were no findings attributable to exposure to the test material. Reproductive performance, in utero survival, and development of the offspring were not affected by treatment. Individual body weights and crown-rump lengths of the fetuses were not altered by treatment. External, visceral, and skeletal examinations of the fetuses did not reveal any remarkable findings.
Conclusions	Under the conditions of this study, Decene Homopolymer does not induce developmental toxicity in rodents following dermal application.
Data Quality	1 - Reliable without restrictions
Reference	Developmental Toxicity Screen in Rats Exposed Dermally to Decene Homopolymer, (1988), Mobil Environmental and Health Sciences Laboratory.
Date last changed	December, 01

CARCINOGENICITY (CAS NO.: 68037-01-4)

Test Substance	**1-Decene Homopolymer, hydrogenated**
CAS No.	**68037-01-4**
Method/Guideline	Other
Type of Study	Dermal Carcinogenicity
GLP	Yes
Year	1990
Species/strain	C3H mice
Sex	Males
No. of animals/sex/dose	50 mice
Route of administration	Dermal
Frequency of Treatment	2 times per week, 104 weeks
Vehicle	None
Remarks on Test Conditions	Decene homopolymer was applied at a dose of 50 µl/application to the interscapular skin twice weekly for 104 weeks. Repeated dermal exposure is the primary route of exposure with industrial use. Mice were examined daily for skin growths, each suspected tumor was collected at the death of the mouse and examined microscopically. Male mice were received at 5-6 weeks of age and quarantined for two weeks. Mice were randomly assigned to treatment groups. During the study, mice were shaved approximately once a week or when necessary. Food and water were available ad libitum. Animals were observed twice daily for morbidity and moribundity. Any animals found moribund or that appeared moribund from the weight and size of the tumor or old age were sacrificed.
Results	Negative
Remarks	No treatment-related tumors were seen. In the negative control group,

	no primary skin tumors developed. Changes to the skin were minimal and nonspecific. Some hyperplasia was observed and deemed to be due to repeated hair removal. In the positive controls, 47 of the 50 mice developed skin tumors. Squamous cell carcinoma was the most common tumor. All mice in this group died by the 37th week. Survival of the treated group (56%) was greater than in the untreated group (42%). In the treated group, skin changes were similar to the negative controls. The interscapular skin did not have any tumors.
Conclusions	Under the conditions of this study, Decene Homopolymer is not carcinogenic in mice following chronic dermal exposure.
Data Quality	1 - Reliable without restrictions
Reference	Dermal Carcinogenicity Study on Decene Homopolymer(1990), Performed by Kettering Laboratory for Mobil Environmental and Health Science Laboratory.
Date last changed	December, 01

ACUTE ORAL TOXICITY (CAS NO.: 151006-60-9)

Test substance	**1-decene/1-dodecene copolymer, hydrogenated (Alkane 5) prepared from 10% 1-dodecene and 90% 1-decene, comprising C10 oligomers [approximately 33% trimer (C30), 51% tetramer (C40), 16% pentamer (C50) and higher] and C12 oligomers. CAS 151006-60-9**
Type	LD50
Species	rat
Strain	Sprague-Dawley
Sex	male/female
Number of animals	10
Vehicle	other: none
Value	> 5000 mg/kg bw
Method	OECD Guide-line 401 "Acute Oral Toxicity"
Year	1995
GLP	Yes
Test condition	A study was performed to assess the acute oral toxicity of the test material in the Sprague-Dawley strain rat. Following a range-finding study, a group of ten fasted animals (five males and five females) was given a single oral dose of undiluted test material at a dose level of 5000 mg/kg bodyweight. Individual bodyweights were recorded on the day of dosing to allow calculation of individual treatment volumes and on Day 14. The animals were observed for deaths or overt signs of toxicity 1, 2.5, and 4 hours after dosing and subsequently once daily for 14 days. They were then killed and subjected to a gross necropsy.
Result	There were no deaths. No signs of systemic toxicity were noted during the study. All animals showed expected gain in body weight during the study. No abnormalities were noted at necropsy. The acute oral median lethal dose (LD50) of the test material in the Sprague-Dawley strain rat was found to be greater than 5000 mg/kg bodyweight.

Conclusion	The acute oral median lethal dose (LD50) of the test material in the Sprague-Dawley strain rat was found to be greater than 5000 mg/kg bodyweight.
Reliability	(1) valid without restriction
Reference	SafePharm Laboratories Limited (1995). Acute Oral Toxicity Study in The Rat. Conducted for Chevron Research and Technology Company, unpublished report.

13.12.2001

ACUTE INHALATION TOXICITY (CAS NO.: 151006-60-9)

Test substance	**1-decene/1-dodecene copolymer, hydrogenated (Alkane 5) prepared from 10% 1-dodecene and 90% 1-decene, comprising C10 oligomers [approximately 33% trimer (C30), 51% tetramer (C40), 16% pentamer (C50) and higher] and C12 oligomers. CAS 151006-60-9**
Type	LC50
Species	rat
Strain	Sprague-Dawley
Sex	male/female
Number of animals	10
Vehicle	other: none
Exposure time	4 hour(s)
Value	> 5.06 mg/l
Method	OECD Guide-line 403 "Acute Inhalation Toxicity"
Year	1995
GLP	Yes

Test Condition	A study was performed to assess the acute inhalation toxicity of the test material, as supplied, by exposing a single group of Sprague-Dawley strain rats (five males and five females) to an aerosol atmosphere. The animals were exposed for four hours using a nose only exposure system. Prior to the start of the study, test material atmospheres were generated within the exposure chamber. During these periods air flow settings, test material input and the sampling system were varied to achieve the required atmospheric concentrations. During the exposure period, temperature, relative humidity, oxygen concentrations and nominal atmospheric concentrations were monitored at regular intervals. The particle size of the generated atmosphere of the test material inside the exposure chamber was determined four times during the exposure period using a Cascade Impactor. Clinical observations were performed hourly during the exposure, immediately at the end of the exposure, one hour after the termination of the exposure and once daily for 14 days. Individual bodyweights were recorded on the day of exposure and on Days 7 and 14. Necropsies were performed on all animals at study termination.
Result	The mean achieved atmosphere concentration was 5.0 mg/L. The mean mass median aerodynamic diameter was 1.3 u. The inspirable fraction (%<4 u) was 90.0%. The geometric standard deviation was 0.42u. No deaths occurred. Common abnormalities noted during the study were wet fur, hunched posture, and piloerection. Incidents of decreased and increased respiratory rate, ptosis and red/brown staining around the eyes were noted. All animals appeared normal 2-3 days following exposure and for the remainder of the study. Normal bodyweight gain was noted during the study. One animal showed dark patches on the lungs but otherwise no abnormalities were detected at necropsy. The acute inhalation median lethal concentration (LC50) of the test material, Alkane 4, in the Sprague-Dawley strain rat was greater than 5.0 mg/L.
Conclusion	The acute inhalation median lethal concentration (LC50) of the test material, Alkane 5, in the Sprague-Dawley strain rat was greater than 5.0 mg/L.
Reliability	(1) valid without restriction
Reference	SafePharm Laboratories Limited (1995). Acute Inhalation Toxicity Study (Nose Only) in The Rat. Conducted for Chevron Research and Technology Company, unpublished report.

13.12.2001

ACUTE DERMAL TOXICITY (CAS NO.: 151006-60-9)

Test substance	**1-decene/1-dodecene copolymer, hydrogenated (Alkane 5) prepared from 10% 1-dodecene and 90% 1-decene, comprising C10 oligomers [approximately 33% trimer (C30), 51% tetramer (C40), 16% pentamer (C50) and higher] and C12 oligomers. CAS 151006-60-9**

Type	LD50
Species	rat
Strain	Sprague-Dawley
Sex	male/female
Number of animals	10
Vehicle	other: none
Value	> 2000 mg/kg bw
Method	OECD Guide-line 402 "Acute dermal Toxicity"
Year	1995
GLP	Yes
Test condition	A study was performed to assess the acute dermal toxicity of the test material in the Sprague-Dawley strain rat. A group of ten animals (five males and five females) was given a single, 24-hour, semi-occluded, dermal application to intact skin at a dose level of 2000 mg/kg bodyweight. Individual bodyweights were recorded on the day of dosing to allow calculation of individual treatment volumes and on Days 7 and 14. The animals were observed for deaths or overt signs of toxicity 1, 2.5, and 4 hours after dosing and subsequently once daily for 14 days. The animals were observed for dermal irritation approximately 30 minutes after bandage removal and on Days 3, 7, 10, and 14. The animals were then killed for gross pathological examination.
Result	There were no deaths. No signs of systemic toxicity or skin irritation were noted during the study. All animals showed expected gain in bodyweight during the study. No abnormalities were noted at necropsy. The acute dermal median lethal dose (LD50) of the test material in the Sprague-Dawley strain rat was found to be greater than 2000 mg/kg bodyweight.
Conclusion	The acute dermal median lethal dose (LD50) of the test material in the Sprague-Dawley strain rat was found to be greater than 2000 mg/kg bodyweight.
Reliability	(1) valid without restriction
Reference	SafePharm Laboratories Limited (1995). Acute Dermal Toxicity Study in The Rat. Conducted for Chevron Research and Technology Company, unpublished report.

13.12.2001

GENETIC TOXICITY 'IN VITRO' (CAS NO.: 151006-60-9)

Test substance	**1-decene/1-dodecene copolymer, hydrogenated (Alkane 5) prepared from 10% 1-dodecene and 90% 1-decene, comprising C10 oligomers [approximately 33% trimer (C30), 51% tetramer (C40), 16% pentamer (C50) and higher] and C12 oligomers. CAS 151006-60-9**
Type	Salmonella typhimurium and Escherichia coli/Mammalian-Microsome Reverse Mutation Assay
System of testing	Bacterial
Concentration	0, 15, 50, 150, 500, 1500, 5000 ug/plate

Cycotoxic conc.	> 5000 ug/plate
Metabolic activation	with and without
Result	negative
Method	OECD Guide-line 471 "Genetic Toxicology: Salmonella thyphimurium Reverse Mutation Assay"
Year	1995
GLP	Yes

Test condition

Salmonella typhimurium strains TA1535, TA1537, TA98, and TA100 and Escherichia coli strain WP2uvrA- were treated with the test material using the Ames plate incorporation method at six dose levels, in triplicate, both with and without the addition of a rat liver homogenate metabolizing system (10% liver S9 in standard co-factors). The S9 concentration was determined in an S9 optimization study. The dose range was determined in a preliminary toxicity assay and was 15 to 5000 ug/plate in the first experiment. A second experiment was performed on a separate day using the same dose range as Experiment 1, fresh cultures of the bacterial strains, and fresh chemical formulations. Vehicle (25% w/w Pluronic F127 in ethanol), untreated (negative) and positive controls were included in each experiment.

For the test, 0.1 mL of bacterial culture, 2.0 mL of top agar, 0.1 mL of the test material formulation, vehicle or positive control and either 0.5 mL of S9 mix or phosphate buffer was mixed together and poured onto the surface of a Vogel-Bonner Minimal agar plate. The plates were incubated for 48 hours at 37C after an initial overnight equilibration period and the frequency of revertant colonies was assessed.

For a substance to be considered positive in this test system, it should have induced a dose-related and statistically significant increase in the revertant count (of at least twice the spontaneous reversion rate) in one or more strains of bacteria in the presence and/or absence of S9 in both experiments. To be considered negative, the number of revertants at each dose level should have been less than twofold the vehicle control frequency. Statistical significance was analyzed using the methods recommended by the UKEMS [Reference: Kirkland, D.J., Ed., Statistical Evaluation of Mutagenicity Test Data, UKEMS sub-committee on Guidelines for Mutagenicity Testing. Report Part III (1989) Cambridge University Press.].

Result

The test material caused no visible reduction in the growth of the bacterial lawn at any dose level either with or without metabolic activation. The test material was therefore tested up to a maximum recommended dose level of 5000 ug/plate. A precipitate was observed at and above 500 ug/plate; this however did not interfere with the scoring of revertant colonies. No significant increase in the frequency of revertant colonies was recorded for any of the bacterial strains with any dose of the test material, either with or without metabolic activation.

The vehicle/suspending agent (Pluronic F127 in ethanol (25% w/w)) and untreated control plates produced counts of revertant colonies within the normal range.

All of the positive control chemicals used in the study induced marked increases in the frequency of revertant colonies, both with and without

	the metabolizing system. The test material was found to be nonmutagenic under the conditions of this test.
Conclusion	The test material was found to be nonmutagenic under the conditions of this test.
Reliability	(1) valid without restriction
Reference	Thompson, P.W. (1995) Salmonella typhimurium and Escherichia coli/mammalian-microsome reverse mutation assay. Report of Safepharm Laboratories Limited, Derby U.K. conducted for Chevron Research & Technology Company, Richmond, CA.
31 October 01	

GENETIC TOXICITY 'IN VIVO' (CAS NO.: 151006-60-9)

Test substance	**1-decene/1-dodecene copolymer, hydrogenated (Alkane 5) prepared from 10% 1-dodecene and 90% 1-decene, comprising C10 oligomers [approximately 33% trimer (C30), 51% tetramer (C40), 16% pentamer (C50) and higher] and C12 oligomers. CAS 151006-60-9**
Type	Micronucleus assay
Species	mouse
Sex	male/female
Strain	CD-1
Route of admin.	i.p.
Exposure period	24, 48 or 72 hours
Doses	1250, 2500 and 5000 mg/kg
Result	negative
Method	OECD Guide-line 474 "Genetic Toxicology: Micronucleus Test"
Year	1995
GLP	yes
Test condition	A study was performed to assess the potential of the test material to produce damage to chromosomes or aneuploidy when administered via the intraperitoneal route to mice. Following a preliminary range-finding study in males and females, the micronucleus study was conducted using the test material at the maximum recommended dose level of 5000 mg/kg with 2500 and 1250 mg/kg as the lower two dose levels. In the micronucleus study, groups of ten mice, five males and five females, were given single intraperitoneal doses of the test material at 1250, 2500, and 5000 mg/kg diluted with arachis oil. Further, 4 groups of 10 mice (5 males and 5 females) were dosed, 3 via the intraperitoneal route with arachis oil and one orally with cyclophosphamide to serve as vehicle and positive controls respectively.

Animals in the vehicle control groups were killed 24, 48 and 72 hours following dosing and positive control group animals were killed 24 hours after exposure. The bone marrow was extracted, and smear preparations were made and stained. The incidence of micronucleated cells per 1000 polychromatic erythrocytes per animal was scored. In addition, the number of normochromatic erythrocytes associated with 1000 erythrocytes were counted; these cells were also scored for incidence of micronuclei.

A positive mutagenic response was demonstrated when a statistically significant and dose responsive increase in the number of micronucleated polychromatic erythrocytes was observed for either the 24, 48, or 72-hour kill times when compared to their corresponding control group. A positive response for bone marrow toxicity was demonstrated when the dose group mean polychromatic to normochromatic ratio was shown to be statistically significantly lower than the concurrent vehicle control group. All data were statistically analysed using appropriate statistical methods as recommended by the UKEMS Sub-committee on Guidelines for Mutagenicity Testing Report, Part III (1989).

Result

There were no premature deaths or clinical signs observed in any of the dose groups. There was no evidence of a statistically significant increase in the frequency of micronucleated polychromatic erythrocytes when compared to the concurrent vehicle control group.

There was no statistically significant change in the PCE/NCE ratio in any of the test material dose groups when compared to their concurrent control groups.

The positive control material produced a marked increase in the frequency of micronucleated polychromatic erythrocytes.

The test material, Alkane 5, was found not to produce an increase in the frequency of micronuclei in polychromatic erythrocytes of mice under the conditions of the test.

Conclusion

The test material, Alkane 5, was considered to be non-genotoxic under the conditions of the test.

Reliability

(1) valid without restriction

Reference

1-decene/1-dodecene copolymer, hydrogenated (Alkane 5) prepared from 10% 1-dodecene and 90% 1-decene, comprising C10 oligomers [approximately 33% trimer (C30), 51% tetramer (C40), 16% pentamer (C50) and higher] and C12 oligomers.

31 October 01

WATER SOLUBILITY (CAS NO.: 163149-28-8)

Test Substance: **CAS No.: 163149-28-8;**
1-Octene, 1-Decene, 1-Dodecene copolymer, hydrogenated

Method/Guideline: OECD 106

Year (guideline):	1993
Type (test type):	Soil Adsorption/Desorption Study
GLP:	Yes
Year (study performed):	1995
Temperature:	24 Deg C
pH value:	No data
Test Conditions: • **Note: Concentration prep., vessel type, replication, test conditions.**	A saturated aqueous solution of the test material was prepared by placing 10 mL of ultrapure water (reverse osmosis/ion exchange system) and 4 mL of the test material in a glass tube and rotary-mixing for 16 hours at 24 Deg. C. After settling, the lower aqueous phase was carefully withdrawn using a 10 mL glass syringe. The water samples were extracted and the extracts were spotted on a Thin Layer Chromatography (TLC) plate, along with a standard corresponding to 100% recovery of the test material from water. Samples were analyzed in duplicate. The method detection limit was 0.4 mg/L.
Results:	Water solubility = <0.4 mg/L (less than limit of quantification with this method).
Units/Value: • **Note: Deviations from protocol or guideline, analytical method.**	TLC spots of the duplicate samples were slightly darker than blank samples, indicating that a "trace" (<0.4 mg/L) amount of the test material was detected in the saturated water samples, but the concentration was too low to be accurately quantified. Water solubility was measured as a requirement for a Soil Adsorption/Desorption (K_{oc}) study, not as part of a water solubility study.
Conclusion:	
Reliability:	(1) Reliable without restriction
Reference:	Stonybrook Laboratories, Inc. 1995. Solubility in Water. Study No. 66471.
Other (source):	ExxonMobil Biomedical Sciences, Inc.

FISH ACUTE TOXICITY (CAS NO.: 163149-28-8)

Test Substance:	**CAS No.: 163149-28-8;** **Octene, 1-Decene, 1-Dodecene copolymer, hydrogenated**
Method/Guideline:	Fish Acute Toxicity Test (EPA 560/6-82-002; OECD 203)
Type (test type):	Fish Acute Toxicity Test; Dispersion Test
GLP:	Yes
Year (study performed):	1994
Species:	Rainbow Trout (*Oncorhynchus mykiss*)

Analytical Monitoring:	Yes (Gas Chromatography - with Flame Ionization Detection)
Exposure Period:	96 hour
Statistical Method:	Binomial Probability Analysis (Stephan, et al., 1978)
Test Conditions: • **Note: Concentration prep. vessel type, volume, replication, water quality parameters, environmental conditions, organisms supplier, age, size, weight, loading.**	Individual Oil/Water Dispersion (OWD) systems were prepared for each treatment level. The test system was designed to maintain the test substance as a dispersion of small droplets throughout the water column. The test substance was added volumetrically, via graduated cylinder, directly to the dispersion system. Each test chamber was a 10-gallon glass aquaria with 30 liters of water, and was equipped with a vertically mounted, motor-driven impeller assembly. The impeller assembly, consisting of 3-blades on a 10-inch stainless steel shaft, was housed in a 2-inch diameter PVC cylinder with 4 horizontal apertures near the bottom. Water and test substance spilling into the top of the cylinder were expelled through the apertures at the bottom. The OWD systems operated continuously for the duration of the test. Twenty fish were randomly assigned to each chamber. No renewal of the test solutions was performed during the test. Samples for chemical analysis were removed from the 99 mg/L, 1020 mg/L, and 5010 mg/L concentrations at 10 minutes and 96 hours after test initiation. Test temperature was 11.7 - 11.8 Deg C., lighting was 16 hours light : 8 hours dark. Dissolved oxygen ranged from 9.6 to 10.1 mg/L and pH ranged from 8.2 to 8.6 during the study. Fish were not fed during the study. Fish Mean Wt.(Control) = 0.38 g; mean standard length = 3.1 cm; test loading = 0.25 g of fish/L.
Results: **Units/Value:** • **Note: Deviations from protocol or guideline, analytical method, biological observations, control survival.**	96-hr LL0 = 5010 mg/L, based on nominal loading levels. Loading Level. / Mean Measured Conc. / % Mortality @ 96 hr. Control / <LOQ* / 0 99 mg/L / <LOQ / 0 510 mg/L / / 0 1020 mg/L / <LOQ / 0 2010 mg/L / / 0 5010 mg/L / <LOQ / 0 *LOQ = Limit Of Quantitation = 87 mg/L
Conclusion:	
Reliability:	Code 1, Reliable without restriction

Reference:	Stonybrook Laboratories, Inc., 1994. Static 96-hour Acute Toxicity Study of MCP-1602 to Rainbow Trout, Study No. 66134.
Other (source):	ExxonMobil Biomedical Sciences, Inc.

INVERTEBRATE ACUTE TOXICITY (CAS NO.: 163149-28-8)

Test Substance:	**CAS No.: 163149-28-8;** **1-Octene, 1-Decene, 1-Dodecene copolymer, hydrogenated**
Method/Guideline:	Daphnia Acute Toxicity Test (EPA 560/6-82-002; OECD 202)
Type (test type):	Daphnia Acute Toxicity Test
GLP:	Yes
Year (study performed):	1994
Species:	Water flea (*Daphnia magna*)
Analytical Monitoring:	Yes (Gas Chromatography - with Flame Ionization Detection)
Exposure Period:	48-hours
Statistical Method:	Binomial Probability Analysis (Stephan, et al., 1978)
Test Conditions: • **Note: Concentration prep. vessel type, volume, replication, water quality parameters, environmental conditions, organisms supplier, age, size, loading.**	Individual test treatment solutions were prepared as Water Accommodated Fractions (WAFs). A measured amount of the test material was added to 1.0L of test water in aspirator bottles. WAFs were stirred for approximately 20 hours with stir bars producing a vortex of less than 25% of the depth of the solution, and then allowed to settle for approximately 4 hours. Three samples were prepared from each aspirator bottle. For each nominal loading, organisms were added to two labeled 250 ml glass chambers containing 200 ml WAF solution; the third bottle was used for measuring initial water quality. 10 daphnids, less than 24-hours old, were randomly assigned to each test chamber. Test chambers were covered with plexiglass sheets. No renewal of the test solutions was performed during the test. Test exposure chambers were maintained at 20± 1 °C. Lighting was 16 hours light: 8 hours dark. Dissolved oxygen levels remained above 60% saturation throughout the test. The pH values ranged between 8.0 to 8.08. Organisms were obtained from in-house cultures.
Results: **Units/Value:** • **Note: Deviations from protocol or guideline, analytical method, biological**	The 48-hr EL_0 = 5,220 mg/L, based on nominal loading levels.

analytical method, biological observations, control survival. **Results: cont'd**	Loading Level. / Measured Conc. / % Mortality @ 48 hr. Control / < LOQ* / 0 360 mg/L / < LOQ / 0 630 mg/L / nm / 0 1,350 mg/L / < LOQ / 0 2610 mg/L / nm / 0 5,220 mg/L WAF / < LOQ / 0 *LOQ = Limit Of Quantitation = 2 mg/L nm = not measured
Conclusion:	
Reliability:	Code 1, Reliable without restriction
Reference:	Stonybrook Laboratories, Inc. 1994. 48-hour Static Acute Toxicity Study of the WAF of MCP-1602 to *Daphnia magna*, Study No. 66135.
Other (source):	ExxonMobil Biomedical Sciences, Inc.

Algal Toxicity (CAS No.: 163149-28-8)

Test Substance:	**CAS No.: 163149-28-8;** **1-Octene, 1-Decene, 1-Dodecene homopolymer, hydrogenated**
Method/Guideline:	Acute Alga InhibitionTest (EPA 560/6-82-002; OECD 201)
Type (test type):	Static Acute Alga Inhibition Test
GLP:	Yes
Year (study performed):	1994
Species/Strain:	Green Alga (*Selenastrum capricornutum*)
Analytical Monitoring:	Yes (Gas Chromatography - with Flame Ionization Detection)
Exposure Period:	72 hour
Statistical Method:	Binomial Probability Analysis (Stephan, et al., 1978)

Test Conditions: • **Note: Concentration prep. vessel type, volume, replication, water quality parameters, environmental conditions, organism culture, age.**	Individual test treatment solutions were prepared as Water Accommodated Fractions (WAFs). Test material was added to 1.0L of algal media in aspirator bottles. The mixing vessels were capped with parafilm and mixed on magnetic stir plates for 20 hours with stir bars producing a vortex of less than 25% of the depth of the solution. After mixing, the solutions were allowed to settle for approximately four hours. The WAF was removed from the bottom of the mixing vessel via the port and used for testing. Test vessels were 125ml glass Erlenmeyer flasks containing 50 mL of treatment solution and algae. Three replicates were prepared for each treatment level. The initial algal cell loading was 1.0×10^4 cells/ml. All test replicates were placed on a shaker table at 100 oscillations per minute during the study. The flasks were covered loosely to facilitate gas exchange. Samples were taken at the end of the 72-hour exposure for cell counts. Nominal treatment levels were 360, 630, 1350, 2610, and 5220 mg/L. Samples for chemical analysis of the control, 360, 1350, and 5220 mg/L treatment levels were below the Limit of Quantitation (LOQ = 2 mg/L). Test temperature was 24 ± 1 Deg. C; lighting was continuous at 450 ± 50 foot-candles. The pH was 7.5 at test initiation.
Results: **Units/Value:** **Measurement (cells/growth)** • **Note: Deviations from protocol or guideline, analytical method, biological observations, control survival.**	72-hr EL_0 = 5220 mg/L, based on biomass. 72-hr NOEL = 5220 mg/L, based on biomass.
Results: cont'd	Loading Level (mg/L) / 72-hr (% Inhibition) / Mean Cell Conc. - 72 hr (cells/ml) Control / n/a / 3.52×10^4 360 / 12.3 / 3.09×10^4 630 / -12.6* / 3.96×10^4 1350 / -6.7* / 3.75×10^4 2610 / -64.0* / 5.77×10^4 5220 / -76.5* / 6.21×10^4 n/a - Not applicable *Stimulatory response
Conclusion:	
Reliability:	Code 2, Reliable with Restrictions Cell growth in the Control did not meet the acceptability requirement of a 16-fold increase. However, growth in the test concentrations indicates that the test material is not inhibitory.

Reference:	Stonybrook Laboratories, Inc. 1994. Static 72-hour Inhibition Study of the WAF of MCP-1602 to Selenastrum capricornutum, Study No. 66137.
Other (source):	ExxonMobil Biomedical Sciences, Inc.

Acute Oral Toxicity (CAS No.: 163149-28-8)

Test Substance	**Octene, Decene, Dodecene Copolymer**
CAS No.	**163149-28-8**
Method/Guideline	Other
Type of Study	Acute Oral
GLP	Yes
Year	1995
Species/strain	Sprague-Dawley rats
Sex	Males/Females
No. of animals/sex/dose	5/sex
Route of administration	Oral gavage
Dose/Concentration Levels	Limit dose: 2 g/kg
Remarks on Test Conditions	Five male and five female young adult rats were fasted overnight and dosed via oral gavage with 2 gm/kg of test material. Body weights were recorded prior to fasting and on days 0, 7, and 14. Food was returned to each animal immediately after dosing. Signs of toxicity were recorded approximately 1/2, 1, and 4 hours after dosing and daily thereafter.
Results	LD_{50} > 2 g/kg
Remarks	All animals survived until study termination. Soft stool was noted in two animals at 4 hours and in two animals on day 1. Chromorhinorrhea was observed in one animal on day 14. No other abnormal clinical signs were observed. There were no gross pathological changes noted at necropsy that were attributed to the test substance.
Conclusions	Under the conditions of this study, octene, decene, dodecene copolymer has a low order of acute toxicity via the oral route of exposure.
Reliability	1 - Reliable without restrictions
Reference	Acute Oral Toxicity in the Sprague-Dawley Rat (1995), Performed by Stonybrook Laboratories, Inc.

Repeated Dose Toxicity (CAS No.: 163149-28-8)

Test Substance CAS No.	**Octene, Decene, Dodecene Copolymer** **163149-28-8**

Method/Guideline	Other
Type of Study	Subchronic Dermal
GLP	Yes
Year	1995
Species/strain	Sprague-Dawley rats
Sex	Males/Females
No. of animals/sex/dose	10/sex/dose
Route of administration	Dermal
Dose/Concentration Levels	0, 125, 500, 2000 mg/kg/day
Remarks on Test Conditions	Rats (10/sex/dose) were exposed dermally five days per week for four weeks at doses of 0, 125, 500, and 2000 mg/kg/day. In addition, two satellite groups (0, 2000 mg/kg/day) were observed for two weeks following the four weeks of dosing to evaluate persistence, delayed effects, and/or recovery. Animals were fitted with Elizabethan collars to minimize ingestion of the test material. The test material was applied to the skin and left uncovered.
Results	NOEL = 500 mg/kg/day NOAEL = 2000 mg/kg/day
Remarks	Treated animals exhibited minimal signs of systemic toxicity. No dermal irritation was observed at the site of exposure. After the fourth week of dosing, there was a slight decrease in body weight in the males of the high dose group. However, this decrease was statistically significant only for the satellite group of animals. Furthermore, female weight gain was not affected. There were no effects on food consumption during the study. During the last week, male rats of the high dose group had statistically higher segmented neutrophil counts than the control. In addition, males of the high-dose satellite group had significant changes in 7 of 20 serum chemistry parameters. Following the two-week recovery period, no hematologic changes were observed in control or treated animals. After the 2-week recovery period, there were also statistical differences between the female controls and the treated satellite group for 2 serum chemistry parameters. Since these changes in serum chemistry parameters were not consistent between the satellite groups and the matching dose group from the main study, the effects were not considered to be biologically significant. No significant macroscopic changes were noted at the main necropsy or the recovery group necropsy. In addition, no organ weight differences attributable to the test material were noted between the control and treatment groups at either interval. Microscopic changes related to treatment were limited to the skin which showed an increased incidence of hyperplasia and hyperkeratosis. However, similar changes were also observed in the control and recovery groups, and thus may be due to repeated shaving of the skin.
Conclusions	Octene, Decene, Dodecene Copolymer has a low order of subchronic toxicity by the dermal route of exposure.
Reliability	2 - Reliable with restrictions – not a guideline study.
Reference	Four-week systemic toxicity study following daily dermal administration to rats, (1995), Mobil Chemical Company.

Genetic Toxicity 'In Vitro' (CAS No.: 163149-28-8)

Test Substance	**Octene, Decene, Dodecene Homopolymer**
CAS No.	**163149-28-8**
Method	Other
Type of Study	Ames
GLP	Yes
Year	1995
Species/Strain	Salmonella typhimurium: TA98, TA100, TA1535, TA1537, TA1538
Metabolic Activation	With and without metabolic activation
Concentrations	0.1, 0.3, 1.0, 3.0, 10.0 µl/50 µl vehicle
Vehicle	Tetrahydrofuran (THF)
Controls	Solvent control and untreated control
Remarks on Test Conditions	Serial dilutions of the test substance were prepared in THF to deliver 0.1, 0.3, 1.0, 3.0, 10.0 µl in 50 µl aliquots per bacterial plate. Positive controls were 2-aminoanthracene, 9-aminoacridine, 2-nitrofluorene, and N-methyl-N'-nitro-N-nitrosoguanidine in DMSO. The S-9 fraction was prepared from the livers of Sprague-Dawley rats induced with Aroclor 1254.
Results	Negative
Remarks for Results	The test material did not induce any toxic effects in the bacteria. None of the strains exhibited reversion frequencies that were substantially different (i.e. doubling of frequency or greater) from spontaneous or solvent controls in two independent assays. The average spontaneous reversion rates for all five strains were also within normal ranges. An increased frequency of revertants was observed with the positive controls when compared to solvent controls.
Conclusion	MCP-1602 is not mutagenic with or without metabolic activation in this test system.
Reliability	1 - Reliable without restrictions
Reference	An Ames Salmonella/Mammalian Microsome Mutagenesis Assay (1995) Performed by Stonybrook Laboratories, Inc.
Date last changed	September, 01

GENETIC TOXICITY 'IN VITRO' (CAS NO.: 163149-28-8)

Test Substance	**Octene, Decene, Dodecene Copolymer**
CAS No.	**163149-28-8**
Method	Other
Type of Study	Chromosomal Aberrations

GLP	Yes
Year	1995
Species/Strain	Cultured Chinese Hamster Ovary (CHO) cells
Metabolic Activation	With and without S9
Concentrations Vehicle	0.10, 0.20, and 0.40 µl/ml vehicle Tetrahydrofuran (THF)
Controls	Positive controls: Mitomycin C, cyclophosphamide
Remarks on Test Conditions	Initially, the test material was tested at a range of concentrations (0.0032 µl/ml to 0.40 µl/ml) to identify a cytotoxic concentration for the main study. The preliminary assay indicated that the high dose (0.40 µl/ml), which is at or above the limit of solubility of the test substance in the medium, was not toxic. The main study was conducted at the following doses: 0.10, 0.20, and 0.40 µl/ml. Cells were exposed to the test chemical for 2 hours in the presence of S9 mix and the cells were harvested 16 hours after initiating treatment. Cells that were not exposed to the S9 fraction were continually exposed to the test substance until cell harvest. The experiment was repeated to confirm the negative findings with the exception that a delayed harvest (40 hours after initiating treatment versus 16 hours) was included.
Results	Negative
Remarks for Results	Both in the presence an absence of metabolic activation, no significant increase in the proportion of cells with chromosomal aberrations was observed when compared to THF controls. No significant increase in the proportion of cells with chromosomal aberrations compared to the solvent control cultures occurred for either harvest times in assays with or without the S9 fraction. Positive and negative controls in both assays responded as expected.
Conclusion	The test substance is not clastogenic under the conditions of this study.
Reliability	1 - Reliable without restrictions
Reference	Assay for Induction of Chromosomal Aberrations in Cultured Chinese Hamster Ovary (CHO) Cells, (1995). Performed by Stonybrook Laboratories, Inc.
Date last changed	September, 01

Partition Coefficient (CAS No.: 1006-62-1)

Test substance	**1-dodecene trimer, hydrogenated (Alkane 4)**
Log pow	> 7.64 at 20° C
Method	
Year	2000
GLP	yes
Test condition	The octanol/water partition coefficient was determined using reverse-phase high performance liquid chromatography (HPLC) with ultraviolet (UV) and refractive index (RI) detectors.

	A Bakerbond C-18 column (0.46 cm id x 25 cm, 5 u packing) was used for separation. A mobile phase of 100% acetonitrile (ACN) that allowed UV detection down to 195 nm was used initially. However, a stronger mobile phase of 25% dichloromethane (DCM) and 75% ACN was required. The isocratic (constant mobile phase composition) mode also allowed for sequential use of the RI, a universal detector detector in HPLC. The retention of polycyclic aromatic hydrocarbons (PAHs) standards with known log Kow values was compared to the retention of the PAO to ascertain the log Kow of the PAO.
Result	The retention times of the polyalphaolefin (PAO), Alkane 4, and nine polycyclic aromatic hydrocarbons (PAHs) with known log Kow values were compared. Neither the ultraviolet (UV) nor refractive index (RI) detectors saw any evidence of PAO elution. The standard mixture of PAHs that eluted had log Kow values of up to 7.64. Therefore, the PAO log Kow value is greater than 7.64 but can be extrapolated to greater than 8. Since coronene eluted at 14.2 minutes and no PAO was detected during the 70 minute analysis time, it can be reasonably concluded that the log Kow of PAO is greater than 8. This high value is emphasized by its limited solubility in the polar solvent acetonitrile. The required use of MTBE implies a very high organic phase preference.
Conclusion	The PAO, Alkane 4, log Kow value is greater than 7.64 but can be extrapolated to greater than 8.
Reliability	(1) valid without restriction
Reference	Seary, M. (2000) Determination of Water Solubility and Octanol/Water Partition Coefficient of C-12 Trimer Polyalphaolefin. Unpublished report conducted by Integrated Laboratory Technologies, Chevron Research and Technology Co., Richmond, CA.

14.03.2001

Water Solubility (CAS 151006-62-1)

Test substance	**1-dodecene trimer, hydrogenated (Alkane 4)** **CAS 151006-62-1**
Value	< 1 other: ppt at ° C
Qualitative	insoluble (< 0.1 mg/L)
Pka	at 25 ° C
PH	at and ° C
Method	
Year	2000
GLP	Yes

Test condition	A low-pressure chromatographic technique was used for concentrating the polyalphaolefin (PAO) to determine its solubility in water. A generator column was prepared with an inert packing material coated with PAO. High-purity water was slowly percolated through the column. The effluent, containing any dissolved PAO, then passed through an octadecyl-bonded phase (C-18) silica collection column. This column retained any organic material from the polar aqueous medium. Acetonitrile and dichloromethane washes were used to elute any PAO from the collector column. The remaining residue was analyzed by gas chromatography-mass spectrometry (GC-MS) to determine the amount of PAO in this fraction. The water solubility of PAO was calculated based on the total volume of water passed through the columns.
Result	The results of the test showed that no polyalphaolefin (PAO) was observed. The only material seen was C-18 carboxylic acid arising from degradation of some of the bonded phase on the collection column. The limit of detection for PAO, <10 ng, was calculated from comparison to injections of standard solutions, pyrene, perylene and coronene. Therefore, the water solubility was calculated to be <1 ppt.
Conclusion	The water solubility of the polyalphaolefin, Alkane 4, was calculated to be <1 ppt.
Reliability	(1) valid without restriction
Reference	Seary, M. (2000) Determination of Water Solubility and Octanol/Water Partition Coefficient of C-12 Trimer Polyalphaolefin. Unpublished report conducted by Integrated Laboratory Technologies, Chevron Research and Technology Co., Richmond, CA.

14.03.2001

ACUTE/PROLONGED TOXICITY TO FISH (CAS NO.: 151006-62-1)

Test substance	**1-dodecene trimer, hydrogenated (Alkane 4)** **CAS 151006-62-1**
Type	semistatic
Species	Oncorhynchus mykiss (Fish, fresh water)
Exposure period	96 hour(s)
Unit	mg/l
Analytical monitoring	yes
NOEC	>= 1000
LC50	> 1000
Method	OECD Guide-line 203 "Fish, Acute Toxicity Test"
Year	1995
GLP	Yes

Test condition

A study was performed to assess the acute toxicity of the test material, Alkane 4, to rainbow trout. Following a preliminary range-finding study, fish were exposed, in two groups of ten, to a Water Accommodated Fraction (WAF) of the test material for a period of 96 hours. A semi-static test regime was employed in the study involving a daily renewal of the test preparations to ensure that the concentrations of the test material remained near nominal and to prevent the build up of nitrogenous waste products. The WAF was prepared by placing the test material on the surface of water to give a 1000 mg/L loading rate which was then stirred with a magnetic stirrer to achieve a vortex depth of approximately 20-25% of the distance to the bottom of the vessel for 24 hours. The mixture was then allowed to stand for 4 hours prior to removing the aqueous phase or WAF by siphon.

The number of mortalities and any adverse reactions to exposure in each test and control vessel were determined 3 and 6 hours after the start of exposure and then daily throughout the study until termination after 96 hours. Duplicate control groups were maintained under identical conditions but not exposed to the test material. The vessels received no auxiliary aeration and were covered to reduce evaporation.

Result

In the Range-finding study the results showed no mortalities at the 100 and 1000 mg/L loading rate Water Accommodated Fractions (WAF's).

The results of the definitive study showed the highest loading rate WAF resulting in 0% mortality to be greater than or equal to 1000 mg/L, the lowest loading rate WAF resulting in 100% mortality to be greater than 1000 mg/L and the No Observed Effect Concentration (NOEC) to be greater than or equal to 1000 mg/L loading rate WAF. The No Observed Effect Concentration is based upon zero mortalities and the absence of any adverse effects of exposure at this concentration.

Analysis of the WAF was carried out by Total Organic Carbon (TOC) analysis. Water samples were taken from the control and each replicate test vessel at 0 hours (fresh test preparations), 24 hours (old test preparations), 72 hours (fresh test preparations) and 96 hours (old test preparations). The results of the TOC analysis showed that, compared to the controls, no significant levels of carbon were detected in the WAFs.

Conclusion

The 96-hour median Lethal Loading Rate (LLR50) for the test material to rainbow trout (Oncorhynchus mykiss), based on nominal loading rates, was greater than 1000 mg/L loading rate Water Accommodated Fraction and correspondingly the No Observed Effect Concentration was greater than or equal to 1000 mg/L loading rate Water Accommodated Fraction.

Reliability

(1) valid without restriction

Reference

SafePharm Laboratories Limited (1995). Acute Toxicity to Rainbow Trout. Conducted for Chevron Research and Technology Company, unpublished report.

27.02.2001

ACUTE TOXICITY TO AQUATIC INVERTEBRATES (CAS NO.: 151006-62-1)

Test substance	**1-dodecene trimer, hydrogenated (Alkane 4)** **CAS 151006-62-1**
Type	static
Species	Daphnia magna (Crustacea)
Exposure period	48 hour(s)
Unit	mg/l
Analytical monitoring	yes
NOEC	>= 1000
EC50	> 1000
Method	OECD Guide-line 202, part 1 "Daphnia sp., Acute Immobilisation Test"
Year	1995
GLP	Yes
Test condition	A study was performed to assess the acute toxicity of the test material, Alkane 4, to Daphnia magna. Following a preliminary range-finding study, forty daphnids (4 replicates of 10 animals) were exposed to a Water Accommodated Fraction (WAF) of the test material for 48 hours under static test conditions. The WAF was prepared by placing the test material on the surface of the water to give a 1000 mg/L loading rate which was then stirred by magnetic stirrer to achieve a vortex depth of approximately 20-25% of the distance to the bottom of the vessel for 24 hours. The mixture was then allowed to stand for 4 hours prior to removing the aqueous phase or WAF by siphon. Immobilization and any adverse reactions to exposure were recorded after 24 and 48 hours. Replicate control groups were maintained under identical conditions but not exposed to the test material. The vessels received no auxiliary aeration and were covered to reduce evaporation.
Result	In the Range-finding study the results showed no immobilization at the 100, and 1000 mg/L loading rate Water Accommodated Fractions (WAF). In the Definitive study, there was no immobilization in 40 daphnids exposed to a 1000 mg/L loading rate WAF for a period of 48 hours. The No Observed Effect Concentration after 24 and 48 hours exposure was greater than or equal to 1000 mg/L loading rate WAF. The No Observed Effect Concentration is based upon zero immobilization at this concentration. Analysis of the Water Accommodated Fractions was carried out by Total Organic Carbon (TOC) analysis on the test preparation at 0 and 48 hours. The results of the TOC analysis showed that compared to the controls, no significant levels of carbon were detected in the WAFs.
Conclusion	The No Observed Effect Concentration after 24 and 48 hours exposure was greater than or equal to 1000 mg/L loading rate WAF. The No Observed Effect Concentration is based upon zero immobilization at this concentration.
Reliability	(1) valid without restriction
Reference	SafePharm Laboratories Limited (1995). Acute Toxicity to Daphnia Magna. Conducted for Chevron Research and Technology Company,

unpublished report.

27.02.2001

TOXICITY TO AQUATIC PLANTS E.G. ALGAE (CAS NO.: 151006-62-1)

Test substance	**1-dodecene trimer, hydrogenated (Alkane 4)** **CAS 151006-62-1**
Species	Selenastrum capricornutum (Algae)
Endpoint	growth rate
Exposure period	96 hour(s)
Unit	mg/l
Analytical monitoring	yes
NOEC	>= 1000
EC50	> 1000
Method	OECD Guide-line 201 "Algae, Growth Inhibition Test"
Year	1995
GLP	Yes

Test condition

A study was performed to assess the effect of the test material, Alkane 4, on the growth of Selenastrum capricornutum. Following a preliminary range-finding study, Selenastrum capricornutum was exposed to a Water Accommodated Fraction (WAF) of the test material (six replicate flasks) for 96 hours under constant illumination and shaking at a temperature of 24oC. The WAF was prepared by placing the test material on the surface of the water to give a 1000 mg/L loading rate which was then stirred to achieve a vortex depth of approximately 20-25% of the distance to the bottom of the vessel for 24 hours. The mixture was then allowed to stand for 4 hours prior to removing the aqueous phase or WAF by siphon. Samples of the algal populations were removed daily, and algal cell concentrations were determined, using an electronic cell counter, for each control and treatment group. Two replicate control groups were maintained under identical conditions but not exposed to the test material.

At the initiation of the study, the algal suspension culture contained a nominal cell density of 10,000 cells per mL.

A Student's t-test was carried out on the area under the growth curve data at 96 hours for the control and 1000 mg/L loading rate WAF test concentration to determine any statistically significant differences between the test and control groups.

Result

In the Range-finding study the results showed no effect on growth at 1000 mg/L Water Accommodated Fraction (WAF).

From the results of the definitive study neither the growth or the biomass of Selenastrum capricornutum were affected by the presence of the test material over the 96-hour exposure period.

All test and control cultures were inspected microscopically at 96 hours. There were no abnormalities detected in any of the control or test cultures.

Analysis of the WAF was carried out by Total Organic Carbon (TOC) analysis on samples from two replicate vessels of treated and control media

at the beginning and end of the test. Given the background level of carbon in the control vessels and also the low level of carbon in the test vessels it is considered that all the results were around the limit of detection of the analytical method. Accordingly the results do not provide definite evidence of stability of the test preparations.

The effect of Alkane 4 on the growth of Selenastrum capricornutum has been investigated and gave median effective loading rate (ELR50) values of greater than 1000 mg/L loading rate WAF. Correspondingly the No Observed Effect Concentration was greater than or equal 1000 mg/L loading rate WAF. These results are based on an initial loading rate of 2000 mg/L which was diluted by the addition of the algal suspension to give an equivalent loading rate of 1000 mg/L.

Conclusion Exposure of Selenastrum capricornutum to the test material gave median Effective Loading Rate (ELR50) values of greater than 1000 mg/L loading rate WAF and correspondingly the No Observed Effect Concentration was greater than or equal 1000 mg/L loading rate WAF.

Reliability (1) valid without restriction

Reference SafePharm Laboratories Limited (1995). Algal Inhibition Test. Conducted for Chevron Research and Technology Company, unpublished report.

27.02.2001

TOXICITY TO MICROORGANISMS E.G. BACTERIA (CAS NO.: 151006-62-1)

Test substance **1-dodecene trimer, hydrogenated (Alkane 4)**
CAS 151006-62-1

Type	aquatic
Species	activated sludge of a predominantly domestic sewage
Exposure period	3 hour(s)
Unit	mg/l
Analytical monitoring	no
EC50	> 1000
NOEC	>= 1000
Method	OECD Guide-line 209 "Activated Sludge, Respiration Inhibition Test"
Year	2000
GLP	Yes

Test condition	A study was performed to assess the effect of the test material on the respiration of activated sewage sludge. Following a preliminary range-finding study, activated sewage sludge was exposed to an aqueous dispersion of the test material at a concentration of 1000 mg/L (three replicate flasks) for a period of 3 hours at 21oC with the addition of a synthetic sewage as a respiratory substrate. 500 mg of test material was dispersed directly into approximately 250 ml of water. Synthetic sewage (16 ml), activated sewage sludge (200 ml) and water were added to a final volume of 500 ml to give the required concentration of 1000 mg/L. The rate of respiration was determined after 30 minutes and 3 hours contact time and compared to data for the control and a reference material, 3,5-dichlorophenol. Observations were made on the test preparations throughout the study period, and the pH of the control, reference material and test material preparations was measured at the end of the exposure period prior to measurement of the oxygen consumption rate. The results of the study were considered valid if (1) the two control respiration rates are within 15% of each other and (2) the EC50 (3-hour contact time) for 3,5-dichlorophenol lies within the range 5 to 30 mg/L.
Result	Alkane 4 EC50 (3hours): >1000 mg/L 3,5-dichlorophenol EC50 (3hours): 11 mg/L Variation in respiration rates of controls 1 and 2 after 3 hours: +/- 3%. The No Observed Effect Concentration (NOEC) after 3 hours was 1000 mg/L. The validation criteria for the control respiration rates and reference material EC50 values were satisfied. It was considered unnecessary and unrealistic to test at concentrations in excess of 1000 mg/L.
Conclusion	The effect of the test material on the respiration of activated sewage sludge micro-organisms gave a 3-hour EC50 of greater than 1000 mg/L. The No Observed Effect Concentration (NOEC) after 3 hours exposure was 1000 mg/L.
Reliability	(1) valid without restriction
Reference	SafePharm Laboratories Limited (2000). Assessment of the Inhibitory Effect of the Respiration of Activated Sewage Sludge. Conducted for Chevron Research and Technology Company, unpublished report.
13.03.2001	

ACUTE ORAL TOXICITY (CAS NO.: 151006-62-1)

Test substance	**1-dodecene trimer, hydrogenated (Alkane 4)** **CAS 151006-62-1**
Type	LD50
Species	rat
Strain	Sprague-Dawley
Sex	male/female
Number of animals	10
Vehicle	other: none
Value	> 5000 mg/kg bw
Method	OECD Guide-line 401 "Acute Oral Toxicity"
Year	1995
GLP	Yes
Test condition	A study was performed to assess the acute oral toxicity of the test material in the Sprague-Dawley strain rat. Following a range-finding study, a group of ten fasted animals (five males and five females) was given a single oral dose of undiluted test material at a dose level of 5000 mg/kg bodyweight. Individual bodyweights were recorded on the day of dosing to allow calculation of individual treatment volumes and on Days 7 and 14. The animals were observed for deaths or overt signs of toxicity 1, 2.5, and 4 hours after dosing and subsequently once daily for 14 days. They were then killed and subjected to a gross necropsy.
Result	There were no deaths. No signs of systemic toxicity were noted during the study. All animals showed expected gain in body weight during the study. No abnormalities were noted at necropsy. The acute oral median lethal dose (LD50) of the test material in the Sprague-Dawley strain rat was found to be greater than 5000 mg/kg bodyweight.
Conclusion	The acute oral median lethal dose (LD50) of the test material in the Sprague-Dawley strain rat was found to be greater than 5000 mg/kg bodyweight.
Reliability	(2) valid without restriction
Reference	SafePharm Laboratories Limited (1995). Acute Oral Toxicity Study in The Rat. Conducted for Chevron Research and Technology Company, unpublished report.

12.03.2001

ACUTE INHALATION TOXICITY (CAS NO.: 151006-62-1)

Test substance	**1-dodecene trimer, hydrogenated (Alkane 4)** **CAS 151006-62-1**
Type	LC50
Species	rat
Strain	Sprague-Dawley
Sex	male/female
Number of animals	10

Vehicle	other: none
Exposure time	4 hour(s)
Value	> 5.06 mg/l
Method	OECD Guide-line 403 "Acute Inhalation Toxicity"
Year	1995
GLP	Yes

Test Condition

A study was performed to assess the acute inhalation toxicity of the test material, as supplied, by exposing a single group of Sprague-Dawley strain rats (five males and five females) to an aerosol atmosphere. The animals were exposed for four hours using a nose only exposure system.

Prior to the start of the study, test material atmospheres were generated within the exposure chamber. During these periods air flow settings, test material input and the sampling system were varied to achieve the required atmospheric concentrations. During the exposure period, temperature, relative humidity, oxygen concentrations and nominal atmospheric concentrations were monitored at regular intervals. The particle size of the generated atmosphere of the test material inside the exposure chamber was determined four times during the exposure period using a Cascade Impactor.

Clinical observations were performed hourly during the exposure, immediately at the end of the exposure, one hour after the termination of the exposure and once daily for 14 days. Individual bodyweights were recorded on the day of exposure and on Days 7 and 14. Necropsies were performed on all animals at study termination.

Result

The mean achieved atmosphere concentration was 5.06 mg/L. The mean mass median aerodynamic diameter was 1.2 u. The inspirable fraction (%<4 u) was 90.1%. The geometric standard deviation was 0.40u. No deaths occurred. Common abnormalities noted during the study were wet fur, hunched posture, and piloerection. Incidents of increased respiratory rate and ptosis and isolated incidents of decreased respiratory rate and red/brown staining on the head were noted. All animals appeared normal on Day 2 following exposure and for the remainder of the study. Normal bodyweight gain was noted during the study. No abnormalities were detected at necropsy. The acute inhalation median lethal concentration (LC50) of the test material, Alkane 4, in the Sprague-Dawley strain rat was greater than 5.06 mg/L.

Conclusion

The acute inhalation median lethal concentration (LC50) of the test material, Alkane 4, in the Sprague-Dawley strain rat was greater than 5.06 mg/L.

Reliability

(2) valid without restriction

Reference

SafePharm Laboratories Limited (1995). Acute Inhalation Toxicity Study (Nose Only) in The Rat. Conducted for Chevron Research and Technology Company, unpublished report.

12.03.2001

ACUTE DERMAL TOXICITY (CAS NO.: 151006-62-1)

Test substance	**1-dodecene trimer, hydrogenated (Alkane 4)** **CAS 151006-62-1**
Type	LD50
Species	rat
Strain	Sprague-Dawley
Sex	male/female
Number of animals	10
Vehicle	other: none
Value	> 2000 mg/kg bw
Method	OECD Guide-line 402 "Acute dermal Toxicity"
Year	1995
GLP	Yes
Test condition	A study was performed to assess the acute dermal toxicity of the test material in the Sprague-Dawley strain rat. A group of ten animals (five males and five females) was given a single, 24-hour, semi-occluded, dermal application to intact skin at a dose level of 2000 mg/kg bodyweight. Individual bodyweights were recorded on the day of dosing to allow calculation of individual treatment volumes and on Days 7 and 14. The animals were observed for deaths or overt signs of toxicity 1, 2.5, and 4 hours after dosing and subsequently once daily for 14 days. The animals were observed for dermal irritation approximately 30 minutes after bandage removal and on Days 3, 7, 10, and 14. The animals were then killed for gross pathological examination.
Result	There were no deaths. No signs of systemic toxicity or skin irritation were noted during the study. All animals showed expected gain in bodyweight during the study. No abnormalities were noted at necropsy. The acute dermal median lethal dose (LD50) of the test material in the Sprague-Dawley strain rat was found to be greater than 2000 mg/kg bodyweight.
Conclusion	The acute dermal median lethal dose (LD50) of the test material in the Sprague-Dawley strain rat was found to be greater than 2000 mg/kg bodyweight.
Reliability	(2) valid without restriction
Reference	SafePharm Laboratories Limited (1995). Acute Dermal Toxicity Study in The Rat. Conducted for Chevron Research and Technology Company, unpublished report.

22.02.2001

REPEATED DOSE TOXICITY (CAS NO.: 151006-62-1)

Test substance	**1-dodecene trimer, hydrogenated (Alkane 4)** **CAS 151006-62-1**
Species	rat
Sex	male/female
Strain	Sprague-Dawley

Route of admin.	unspecified
Exposure period	28 days
Frequency of treatment	daily
Post obs. period	14 days
Doses	0, 1000
Control group	yes, concurrent no treatment
NOAEL	= 1000 mg/kg bw
Method	OECD Guide-line 407 "Repeated Dose Oral Toxicity - Rodent: 28-day or 14-d Study"
Year	1995
GLP	Yes

Test condition

The test material was administered by gavage to a group of five male and five female Sprague-Dawley CD strain rats for twenty-eight consecutive days at a dose level of 1000 mg/kg/day. A control group of five males and five females remained untreated throughout the study period but was otherwise handled in an identical manner to the test animals. Two satellite groups, each of five males and five females, were similarly treated at 1000 mg/kg/day or remained untreated respectively; satellite groups were maintained without treatment for a further fourteen days following the end of the dosing period. Clinical signs, bodyweight, and food and water consumption were monitored during the study. Hematology and blood chemistry were evaluated for all main group animals during the final week of dosing and for satellite group animals at the end of the treatment-free period. All animals were subjected to a gross necropsy examination. The following organs were weighed: adrenals, brain, gonads, heart, kidneys, liver, pituitary, spleen. Histopathological evaluation of the following tissues from main test and control animals was performed: adrenals, heart, kidneys, liver, spleen, testes, macroscopically observed lesions.

Result

There were no deaths during the study. No clinically observable signs of toxicity were detected in test or control animals throughout the study period. No adverse effect on bodyweight development was detected. No adverse effect on dietary intake was detected. No overt intergroup differences in water consumption were detected. No treatment-related effects were detected for hematology, blood chemistry, or organ weights. No treatment-related macroscopic abnormalities were detected at necropsy, and no treatment-related microscopic changes were observed.

Oral administration of the test material, Alkane 4, to rats for a period of twenty-eight consecutive days at a dose level of 1000 mg/kg/day produced no treatment-related changes in the parameters measured. The "No Observed Effect Level" (NOEL) is therefore considered to be 1000 mg/kg/day.

Conclusion

Oral administration of the test material, Alkane 4, to rats for a period of twenty-eight consecutive days at a dose level of 1000 mg/kg/day produced no treatment-related changes in the parameters measured. The "No Observed Effect Level" (NOEL) is therefore considered to be 1000 mg/kg/day.

Reliability

(1) valid without restriction

Reference	SafePharm Laboratories Limited (1995). Twenty-Eight Day Sub-Acute Oral (Gavage) Toxicity Study in the Rat - Limit Test, Including Recovery Groups. Conducted for Chevron Research and Technology Company, unpublished report.

28.02.2001

GENETIC TOXICITY 'IN VITRO' (CAS NO.: 151006-62-1)

Test substance	**1-dodecene trimer, hydrogenated (Alkane 4)** **CAS 151006-62-1**
Type	other: Salmonella typhimurium and Escherichia coli/Mammalian-Microsome Reverse Mutation Assay
System of testing	Bacterial
Concentration	0, 15, 50, 150, 500, 1500, 5000 ug/plate
Cycotoxic conc.	> 5000 ug/plate
Metabolic activation	with and without
Result	negative
Method	OECD Guide-line 471 "Genetic Toxicology: Salmonella thyphimurium Reverse Mutation Assay"
Year	1995
GLP	Yes

Test condition

Salmonella typhimurium strains TA1535, TA1537, TA98, and TA100 and Escherichia coli strain WP2uvrA- were treated with the test material using the Ames plate incorporation method at six dose levels, in triplicate, both with and without the addition of a rat liver homogenate metabolizing system (10% liver S9 in standard co-factors). The dose range was determined in a preliminary toxicity assay and was 15 to 5000 ug/plate in the first experiment. A second experiment was performed on a separate day using the same dose range as Experiment 1, fresh cultures of the bacterial strains, and fresh chemical formulations. Vehicle (25% w/w Pluronic F127 in ethanol), untreated (negative) and positive controls were included in each experiment.

For the test, 0.1 mL of bacterial culture, 2.0 mL of top agar, 0.1 mL of the test material formulation, vehicle or positive control and either 0.5 mL of S9 mix or phosphate buffer was mixed together and poured onto the surface of a Vogel-Bonner Minimal agar plate. The plates were incubated for 48 hours at 37C after an initial overnight equilibration period and the frequency of revertant colonies was assessed.

For a substance to be considered positive in this test system, it should have induced a dose-related and statistically significant increase in the revertant count (of at least twice the spontaneous reversion rate) in one or more strains of bacteria in the presence and/or absence of S9 in both experiments. To be considered negative, the number of revertants at each dose level should have been less than twofold the vehicle control frequency. Statistical significance was analyzed using the methods recommended by the UKEMS [Reference: Kirkland, D.J., Ed., Statistical Evaluation of Mutagenicity Test Data, UKEMS sub-committee on Guidelines for Mutagenicity Testing. Report Part III (1989) Cambridge University Press.].

	The test material formulations were assessed for concentration, stability and homogeneity. The formulations were shown to be stable and the concentrations were found to be within +/-10% of nominal.
Result	The test material caused no visible reduction in the growth of the bacterial lawn at any dose level either with or without metabolic activation. The test material was therefore tested up to a maximum recommended dose level of 5000 ug/plate. A precipitate was observed at and above 1500 ug/plate; this however did not interfere with the scoring of revertant colonies. No significant increase in the frequency of revertant colonies was recorded for any of the bacterial strains with any dose of the test material, either with or without metabolic activation. The vehicle/suspending agent (Pluronic F127 in ethanol (25% w/w)) and untreated control plates produced counts of revertant colonies within the normal range. All of the positive control chemicals used in the study induced marked increases in the frequency of revertant colonies, both with and without the metabolizing system. The test material was found to be nonmutagenic under the conditions of this test.
Conclusion	The test material was found to be nonmutagenic under the conditions of this test.
Reliability	(1) valid without restriction
Reference	SafePharm Laboratories Limited (1995). Salmonella typhimurium and Escherichia coli/Mammalian-Microsome Reverse Mutation Assay. Conducted for Chevron Research and Technology Company, unpublished report.

12.03.2001

GENETIC TOXICITY - IN VITRO (CAS NO.: 151006-62-1)

Test substance	**1-dodecene trimer, hydrogenated (Alkane 4)** **CAS 151006-62-1**
Type	Mammalian Cell Gene Mutation Test
System of testing	CHO HGPRT
Concentration	313, 625, 1250, 2500, 5000 ug/ml
Cycotoxic conc.	> 5000 ug/ml
Metabolic activation	with and without
Result	negative
Method	OECD Guide-line 476 "Genetic Toxicology: In vitro Mammalian Cell Gene Mutation Test"
Year	2001
GLP	Yes
Test condition	Chinese hamster ovary cells treated with the test material were evaluated for gene mutations at the HGPRT locus with duplicate

cultures, together with vehicle (ethanol) and positive controls.

A rangefinding test was conducted to assess toxicity of the test article to the cells. In the non-activated system, concentrations of 0.5 to 5000 ug/mL had relative cloning efficiencies (RCE) ranging from 97% to 73%. In the activated system, the RCEs ranged from 122% to 80%.

In Experiment 1, dose levels of 313, 625, 1250, 2500 and 5000 ug/mL were tested. Cultures tested with and without an induced rat liver homogenate metabolizing system (10% S9 in standard co-factors, 2% S9 final concentration) were exposed for 4 hours, after which the cells were washed, trypsinized and seeded for parallel cytotoxicity and mutant expression determination. For cytotoxicity, cells were seeded in 3 plates for each replicate at a density of 200 cells/60 mm dish and incubated for 7 days. For expression of 6-thioguanine (TG)-resistant mutants (HGPRT locus), cells were subcultured at a density of $2x10^6$ cells/150 cm^2 flask and subcultured at 2- to 3-day intervals for a period of 9 days. After the expression period, the cells from each treated replicate were harvested and seeded in 12 100 mm plates at a density of $2x10^5$ cells/plate. To determine the cloning efficiency of the cells at the time of selection, 200 cells/60 mm dish were plated in triplicate in cloning medium. All clonable test doses and positive and solvent controls were cloned for mutant selection. Cultures were incubated for 7 days. After the incubation period, the colonies were washed, fixed, stained, and counted for cloning efficiency and mutant selection.

Results were confirmed in a second experiment using the same procedures and dose levels.

Results were analyzed by the Cochran-Armitage test for trend and the Fisher-Irwin exact test for group comparisons for proportions. Within group comparisons were made by the Fisher-Irwin exact test.

The test results were considered to have caused a positive response if the test article yielded an average mutant frequency greater than 15 mutants per $1x10^6$ surviving cells and showed more than a significant (statistically or 2-fold) increase in the number of mutants per $1\text{-}10^6$ surviving cells over that of the concurrent and historical solvent controls. In the absence of a positive dose-response trend, at least 2 consecutive test doses must have shown a significant increase in the number of mutants.

Result

All vehicle (solvent) controls gave frequencies of mutations within the range expected. All the positive control treatments gave significant increases in mutant frequency indicating the satisfactory performance of the test and of the activity of the metabolizing system. In the first mutation assay, the RCEs ranged from 92% to 77% and 111% to 89% with and without metabolic activation, respectively. In the confirmatory assay, RCEs ranged from 50% to 23% and 89% to 52% with and without activation, respectively.

In the first experiment with activation, at 625 ug/mL, a significant increase in mutant frequency was seen compared to the solvent control [4, 4, 9, 4, 5, 2 mutants/10^6 surviving cells at 0, 313, 625, 1250, 2500, and 5000 ug/mL, respectively]; however, the increase was not significant when compared to the historical control [9 mutants/10^6 surviving cells].

The same was true for the 2500 ug/mL dose level with activation in the confirmatory assay: 1, 3, 1, 3, 8, 3 mutants/10^6 surviving cells at 0, 313, 625, 1250, 2500, and 5000 ug/mL, respectively].

The positive controls caused a significant increase in mutant frequencies and all criteria for a valid assay were met.

The test material was considered to be negative in this assay.

Conclusion The test material was shown to be non-mutagenic when tested under the conditions of this assay.

Reliability (1) valid without restriction

Reference SITEK Research Laboratories (2001). Test for Chemical Induction of Gene Mutation at the HGPRT Locus in Cultured Chinese Hamster Ovary (CHO) Cells With and Without Metabolic Activation With a Confirmatory Assay. Conducted for Chevron Research and Technology Company, unpublished report.

12-10-2001

GENETIC TOXICITY - IN VITRO (CAS NO.: 151006-62-1)

Test substance **1-dodecene trimer, hydrogenated (Alkane 4)**
CAS 151006-62-1

Type	Chromosomal aberration test
System of testing	Human Lymphocyte
Concentration	39, 78.1, 156.25, 312.5, 625, 1250, 2500, 5000 ug/ml
Cycotoxic conc.	> 5000 ug/ml
Metabolic activation	with and without
Result	negative
Method	OECD Guide-line 473 "Genetic Toxicology: In vitro Mammalian Cytogenetic Test"
Year	1995
GLP	Yes

Test condition Human lymphocytes treated with the test material were evaluated for chromosome aberrations with duplicate cultures, together with vehicle (ethanol) and positive controls.

In Experiment 1, 8 dose levels ranging from 39 to 5000 ug/ml were tested. Cultures with an induced rat liver homogenate metabolizing system (10% S9 in standard co-factors) were exposed for 4 hours, after which the medium was replaced and the cultures were re-incubated for a further 16 hours. Cultures without metabolic activation were treated continuously for 20 hours. Mitotic indices demonstrated that there was no toxicity. Therefore, the top three dose levels (1250, 2500, and 5000 ug/ml) were evaluated for chromosome aberrations and polyploidy.

Results were confirmed in a second experiment. The cultures with metaboloc activation were treated for 4 hours and harvested 16 hours (concentrations of 625, 1250, 2500, 5000 ug/ml) and 40 hours (1250, 2500, 5000 ug/ml) later. Positive controls were evaluated only in the 20-hour harvest cultures. The dose levels selected for metaphase analysis (1250, 2500, and 5000 ug/ml for the 20hr harvests and 5000 ug/ml for the 44 hr harvests) were selected on the basis of toxicity demonstrated by the mitotic index. Slides were coded and blindly scored. A total of 2000 lymphocyte cell nuclei were counted and the number of cells in metaphase recorded and expressed as the mitotic index and as a percentage of the vehicle control value. Where possible, the first 100 consecutive well-spread metaphases from each culture were counted, and if the cell had 46 or more chromosomes, any gaps, breaks or rearrangements were noted. The frequency of cells with aberrations (both including and excluding gaps) and the frequency of polyploid cells was compared, where necessary, with the concurrent vehicle control value using Fisher's Exact test.

The test material formulations were assessed for concentration, stability and homogeneity. The formulations were shown to be stable and the concentrations were found to be within +/-10% of nominal.

Result

All vehicle (solvent) controls gave frequencies of cells with aberrations within the range expected for normal human lymphocytes. All the positive control treatments gave significant increases in the frequency of cells with aberrations indicating the satisfactory performance of the test and of the activity of the metabolizing system. The test material, induced no statistically significant increases in the frequency of cells with aberrations or polyploid cells. The test material was shown to be nonclastogenic to human lymphocytes in vitro.

Conclusion

The test material was shown to be nonclastogenic to human lymphocytes in vitro.

Reliability

(2) valid without restriction

Reference

SafePharm Laboratories Limited (1995). Chromosome Aberration Test in Human Lymphocytes. Conducted for Chevron Research and Technology Company, unpublished report.

12.03.2001

GENETIC TOXICITY 'IN VIVO' (CAS NO.: 151006-62-1)

Test substance **1-dodecene trimer, hydrogenated (Alkane 4)**
CAS 151006-62-1

Type	Micronucleus assay
Species	mouse
Sex	male/female
Strain	CD-1
Route of admin.	i.p.
Exposure period	24, 48 or 72 hours
Doses	1250, 2500 and 5000 mg/kg
Result	negative

Method	OECD Guide-line 474 "Genetic Toxicology: Micronucleus Test"
Year	1995
GLP	yes

Test condition

A study was performed to assess the potential of the test material to produce damage to chromosomes or aneuploidy when administered via the intraperitoneal route to mice. Following a preliminary range-finding study in males and females, the micronucleus study was conducted using the test material at the maximum recommended dose level of 5000 mg/kg with 2500 and 1250 mg/kg as the lower two dose levels.

In the micronucleus study, groups of ten mice, five males and five females, were given single intraperitoneal doses of the test material at 1250, 2500, and 5000 mg/kg diluted with arachis oil. Further, 4 groups of 10 mice (5 males and 5 females) were dosed, 3 via the intraperitoneal route with arachis oil and one orally with cyclophosphamide to serve as vehicle and positive controls respectively.

Animals in the vehicle control groups were killed 24, 48 and 72 hours following dosing and positive control group animals were killed 24 hours after exposure. The bone marrow was extracted, and smear preparations were made and stained. The incidence of micronucleated cells per 1000 polychromatic erythrocytes per animal was scored. In addition, the number of normochromatic erythrocytes associated with 1000 erythrocytes were counted; these cells were also scored for incidence of micronuclei.

A positive mutagenic response was demonstrated when a statistically significant and dose responsive increase in the number of micronucleated polychromatic erythrocytes was observed for either the 24, 48, or 72-hour kill times when compared to their corresponding control group. A positive response for bone marrow toxicity was demonstrated when the dose group mean polychromatic to normochromatic ratio was shown to be statistically significantly lower than the concurrent vehicle control group. All data were statistically analysed using appropriate statistical methods as recommended by the UKEMS Sub-committee on Guidelines for Mutagenicity Testing Report, Part III (1989).

Result

There were no premature deaths or clinical signs observed in any of the dose groups. There was a small statistically significant increase in the frequency of micronucleated polychromatic erythrocytes in the 24-hour 5000 mg/kg test material dose group when compared to the concurrent vehicle control group. The response was not part of a dose-related effect, was within the current historical range for 24-hr vehicle control groups, and was, therefore considered to be spurious and of no toxicological significance.

There was no statistically significant change in the PCE/NCE ratio in any of the test material dose groups when compared to their concurrent control groups.

The positive control material produced a marked increase in the frequency of micronucleated polychromatic erythrocytes.

The test material, Alkane 4, was found not to produce a toxicologically significant increase in the frequency of micronuclei in polychromatic erythrocytes of mice under the conditions of the test.

Conclusion	The test material, Alkane 4, was found not to produce a toxicologically significant increase in the frequency of micronuclei in polychromatic erythrocytes of mice under the conditions of the test.
Reliability	(1) valid without restriction
Reference	SafePharm Laboratories Limited (1995). Micronucleus Test in the Mouse. Conducted for Chevron Research and Technology Company, unpublished report.

12.03.2001

OTHER RELEVANT INFORMATION (CAS NO.: 151006-62-1)

Test substance	**1-dodecene trimer, hydrogenated (Alkane 4)** **CAS 151006-62-1**
Type	other: The Potential Absorption and Metabolism of Alkane 4 (C36 Polyalphaolefin hydrogenated C12 trimer)
Test condition	The aim of this report is to examine the literature data concerning the absorption and metabolism of Alkane 4 (a paraffin, a long chain (C36) branched alkane) and related substances in order to determine if there is a need to undertake toxicological testing at European Union level 1 and 2. Normally, oral administration is the preferred route of administration for level 1 and 2 toxicity tests, thus this report concentrates on information on absorption from the gastro-intestinal tract. The limited information on the absorption of Alkane 4 was available from the base set tests. Other relevant information was needed. Data was also reviewed from shorter chain alkanes (C16-C20, C29 and C30), other polyalphaolefins, mineral oils, petroleum waxes and hydraulic fluids. Relevant tests are normally conducted in rats, therefore, the review concentrated on that species.
Conclusion	The conclusions that can be drawn from the information in this review are: (1) Alkane 4 meets the US specification for mineral oils that may be used as components of non-food articles intended for use in contact with food and is a polyalphaolefin. It is a 36 carbon molecule. (2) The physicochemical parameters for Alkane 4 and the results of toxicity studies conducted as part of the base set test requirements suggest that Alkane 4 may not be absorbed. (3) Studies in the rat suggest that only limited amounts of the alkanes present in mineral hydrocarbons are absorbed, and that higher molecular weight material is less likely to be absorbed than lower molecular weight material. (4) Structure activity relationship studies indicate that alkanes with 36 carbon atoms are unlikely to be absorbed. (5) By analogy with C16-C29 alkanes, in the event of absorption taking place the first steps in any expected metabolism would be oxidation to the alcohol and formation fo the fatty acid. The product would enter the metabolic pathways described for fatty acids derived from food.

(6) Should absorption occur, it would be expected that the pathologic effects seen would be those associated with an excess intake of lipid like material. Although such effects were seen in rats following oral administration of mineral hydrocarbons, no pathologic effects were noted in studies whem mineral oils and waxes consisting of hydrocarbons with high molecular weights were fed.

In view of the need to pay proper attention to animal welfare and to minimize the use of animals in toxicity testing, these conclusions indicate that it would be inappropriate to undertake further toxicity studies on Alkane 4 at European Union levels 1 and 2.

Reliability (1) valid without restriction

Reference Illing, P. (2000) On the Potential Absorption and Metabolism of Alkane 4. Unpublished report prepasred for Chevron Chemical Company by Paul Illing Consultancy Services, Wirral, UK, and submitted to the UK Health and Safety Executive for Level 2 New Chemical Notification of Alkane 4.